

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 422

[CMS-4190-FC4]

RIN 0938-AT97

Medicare Program; Maximum Out-of-Pocket (MOOP) Limits and Service Category Cost Sharing Standards

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Final rule with comment period.

SUMMARY: This final rule with comment period (FC) will finalize the two remaining proposals from the proposed rule titled "Medicare and Medicaid Programs; Contract Year 2021 and 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly" which appeared in the Federal Register on February 18, 2020 (February 2020 proposed rule). The two proposals being finalized here from the February 2020 proposed rule include the maximum out-of-pocket (MOOP) limits for Medicare Parts A and B services and cost sharing limits for Medicare Parts A and B services, including service category cost sharing limits and per member per month actuarial equivalence cost sharing. In addition, CMS is requesting comments in section III of this FC on new or different ways to update and change cost sharing limits in future years for service categories subject to the regulations, including mental health services.

DATES: *Effective date*: These regulations are effective on [INSERT DATE 60 DAYS AFTER THE DATE OF PUBLICATION IN THE **FEDERAL REGISTER**].

Applicability date: The provisions in this rule will apply to coverage beginning January 1, 2023.

Comment date: To be assured consideration, comments on section III. of this FC must be received at one of the addresses provided below, by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE **FEDERAL REGISTER**].

ADDRESSES: In commenting, please refer to file code CMS-4190-FC4.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

- 1. <u>Electronically</u>. You may submit electronic comments on this regulation to **http://www.regulations.gov**. Follow the "Submit a comment" instructions.
 - 2. By regular mail. You may mail written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-4190-FC4,

P.O. Box 8013,

Baltimore, MD 21244-8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By express or overnight mail. You may send written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-4190-FC4,

Mail Stop C4-26-05,

7500 Security Boulevard,

Baltimore, MD 21244-1850.

For information on viewing public comments, see the beginning of the "SUPPLEMENTARY INFORMATION" section.

FOR FURTHER INFORMATION, CONTACT: Cali Diehl, (410) 786-4053 or

Cali.Diehl@cms.hhs.gov.

SUPPLEMENTARY INFORMATION:

<u>Inspection of Public Comments</u>: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: http://www.regulations.gov. Follow the search instructions on that Web site to view public comments.

CMS will not post on Regulations.gov public comments that make threats to individuals or institutions or suggest that the individual will take actions to harm the individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

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I. Executive Summary and Background

A. Executive Summary

1. Purpose

This final rule with comment period (FC) makes policy changes in alignment with federal laws related to the Medicare Advantage (MA or Part C) program from the 21st Century Cures Act (Pub. L.114-255). The rule also includes regulatory changes to strengthen and improve the Part C program by codifying in regulation several CMS policies previously adopted through the annual Call Letter and other guidance documents to interpret and implement rules regarding benefits in MA plans.

In this FC, we are addressing the two remaining proposals from the February 2020 proposed rule that were not addressed in the June 2020 final rule (85 FR 33796) and the January 2021 final rule (86 FR 5864): (1) Maximum Out-of-Pocket (MOOP) Limits for Medicare Parts A and B Services (§§ 422.100 and 422.101); and (2) Service Category Cost Sharing Limits for Medicare Parts A and B Services and per Member per Month Actuarial Equivalence Cost Sharing (§§ 422.100 and 422.113). The changes to the proposals we are finalizing in this FC range from minor edits, reorganizations, corrections, and clarifications to substantive modifications based on the comments received, operational considerations (such as, changes stemming from the timing of this FC), and additional implementation of antidiscrimination requirements (such as, to support equitable access to plans for beneficiaries with high health needs). In so doing, this FC addresses the following needs for federal regulatory action:

• The provisions relating to MOOP and cost sharing limits improve the operation of the MA program by making updates to reflect changes in Medicare FFS data projections (thereby ensuring the government program does not use outdated data) and clarifying existing policies (thereby answering questions regulated parties may have). Given the context of these provisions

is a federal program, a federal regulatory approach is appropriate with respect to these provisions.

- The provisions also codify subregulatory guidance, which is an improvement in that regulated parties and CMS will have greater clarity regarding the application of these policies as a rule. Given the context of these provisions is a federal program, a federal regulatory approach is appropriate with respect to these provisions.
- 2. Summary of the Major Provisions
- a. Maximum Out-of-Pocket (MOOP) Limits for Medicare Parts A and B Services (§§ 422.100 and 422.101)

Section 1852(b)(1) of the Act prohibits discrimination by MA organizations on the basis of health status-related factors and directs that CMS may not approve an MA plan if CMS determines that the design of the plan and its benefits are likely to substantially discourage enrollment by certain MA eligible individuals. In a 2010 final rule, under the authority of sections 1852(b)(1)(A), 1856(b)(1), and 1857(e)(1) of the Act, CMS added §§ 422.100(f)(4) and (5) and 422.101(d)(2) and (3), effective for coverage in 2011, to require all MA plans (including employer group waiver plans (EGWPs) and special needs plans (SNPs)) to establish limits on enrollee out-of-pocket cost sharing for Parts A and B services that do not exceed the annual limits set by CMS (75 FR 19709 and 19711). Setting MOOP limits is an important step to ensure plan designs are not discriminatory and protect beneficiaries from significant changes in out-of-pocket costs regardless of the MA plan they choose. MA EGWPs must follow all relevant MA regulations and guidance unless CMS has specifically waived a requirement using its statutory authority under section 1857(i) of the Act. Section 1858(b)(2) of the Act requires a limit on in-network and out-of-pocket expenses for enrollees in Regional Preferred Provider Organization (RPPO) MA plans. MA Local PPO (LPPO) plans, under § 422.100(f)(5), and RPPO plans, under section 1858(b)(2) of the Act and § 422.101(d)(3), are required to have two maximum out-of-pocket (MOOP) limits (also called catastrophic limits) calculated by CMS

annually, including-- (1) an in-network limit; and (2) a total catastrophic (combined) limit that includes both in-network and out-of-network items and services covered under Parts A and B. Relying on the same statutory authority, we proposed amendments to the regulations at § 422.100(f)(4) and (5) and §422.101(d)(2) and (3) to specify how these MOOP limits will be set for 2022 and subsequent years. In addition, our proposals made adjustments to current policy based on statutory changes that are relevant to how CMS calculates benefit category cost sharing limits.

We proposed to codify our current practices for setting MOOP limits with some revisions, including explicitly addressing authority to set up to three different MOOP limits. In addition, we proposed to conduct a multiyear transition of end-stage renal disease (ESRD) costs into the methodology for setting MOOP limits. Section 1851(a)(3) of the Act, as amended by section 17006 of the 21st Century Cures Act, amended the Medicare statute to permit Medicare beneficiaries with diagnoses of ESRD to enroll in MA plans beyond the previous enrollment limitations, beginning in contract year 2021. Enrollment impacts from section 17006 of the Cures Act are addressed in sections III.A., VII.B.3., and VIII.D.1. of the June 2020 final rule (85 FR 33796). Before the amendments made by the Cures Act were effective for contract year 2021, individuals diagnosed with ESRD could not enroll in a MA plan, subject to limited exceptions. Generally, those exceptions included the following circumstances: an individual that developed ESRD while enrolled in a MA plan could remain in that plan; an ESRD individual enrolled in a plan which was terminated or discontinued had a one-time opportunity to join another plan; or, an individual could enroll in a special needs plan that had obtained a waiver to enroll individuals with ESRD. We explained that the data we use to calculate the MOOP limits should also incorporate the out-of-pocket expenditures of beneficiaries with diagnoses of ESRD. which we are referring to in this FC as "ESRD costs," to reflect this statutory change. Finally, we proposed safeguards to protect against excessive changes in the MOOP limit during and after the ESRD cost transition.

We are finalizing these MOOP proposals generally as proposed with changes to apply the provisions beginning in contract year 2023 rather than 2022, make modifications to be responsive to comments (including adoption of a transition schedule), and improve and clarify the methodology. A complete discussion of changes from the February 2020 proposed rule is available in section II.A. of this FC.

b. Service Category Cost Sharing Limits for Medicare Parts A and B Services and per Member per Month Actuarial Equivalence Cost Sharing (§§ 422.100 and 422.113)

Section 1852 of the Act imposes a number of requirements that apply to the cost sharing and benefit design of MA plans. First, section 1852(a)(1)(B) of the Act specifies that MA plans may not charge enrollees higher cost sharing than is charged under original Medicare for chemotherapy administration services (which we have implemented as including Part B – chemotherapy/radiation drugs integral to the treatment regimen), skilled nursing care, and renal dialysis services. This provision is currently reflected in §§ 417.454(e) (for cost plans) and 422.100(j) (for MA plans). We proposed to restructure paragraph (j) and codify additional cost sharing limits for other services. We did not propose to change cost plan cost sharing standards. In addition, after publication of the February 2020 proposed rule, the Families First Coronavirus Response Act (Pub. L. 116-127) amended section 1852 of the Act to prohibit MA plans from charging enrollees higher cost sharing than is charged under original Medicare for COVID-19 testing and testing-related services identified in section 1833(cc)(1) for which payment would be payable under a specified outpatient payment provision described in section 1833(cc)(2) during the period from March 18, 2020 through to the end of the emergency period described in section 1135(g)(1)(B) (namely, the COVID-19 public health emergency). The Coronavirus Aid, Relief, and Economic Security Act (Pub. L. 116-136) amended section 1852(a)(1)(B) to require MA plans have cost sharing that does not exceed cost sharing in Original Medicare for a COVID-19 vaccine and its administration described in section 1861(s)(10)(A) of the Act.

Second, section 1852(a)(1)(B)(i) of the Act provides that the MA organization must

cover, subject to limited exclusions, the benefits under Parts A and B (that is, basic benefits as defined in § 422.100(c)) with cost sharing that does not exceed or is at least actuarially equivalent to cost sharing in original Medicare in the aggregate; this is repeated in a bid requirement under section 1854(e)(4) of the Act. We have addressed and implemented this requirement in several regulations, including §§ 422.101(e), 422.102(a)(4), and 422.254(b)(4).

Third, section 1852(a)(1)(B)(iv) of the Act authorizes CMS to add to the list of items and services for which MA cost sharing may not exceed the cost sharing levels in original Medicare.

Fourth, section 1852(b)(1) of the Act prohibits discrimination by MA organizations on the basis of health status-related factors and directs that CMS may not approve an MA plan if CMS determines that the design of the plan and its benefits are likely to substantially discourage enrollment by certain MA eligible individuals. The requirements under § 422.100(f)(4) and (5) that impose MOOP limits on MA plans are based on this anti-discrimination provision by requiring MA local plans to have limits on out of pocket spending by enrollees in order to ensure that beneficiaries with high health needs are not dissuaded from enrolling in an MA plan; while the requirements under § 422.101(d)(2) and (3) implement the statutory catastrophic limits imposed on regional MA plans under section 1858(b) of the Act, those limits similarly protect enrollees with high health needs and avoid discouraging them from enrollment in MA plans. Paragraph (f)(6) provides that cost sharing must not be discriminatory by imposing cost sharing limits. Imposing limits on cost sharing for covered services is an important way to ensure that the cost sharing aspect of an MA plan design does not discriminate against or discourage enrollment of beneficiaries who have high health care needs and who need specific services. CMS issued annual limits on cost sharing for covered services and guidance addressing discriminatory cost sharing, as applied to specific benefits and to categories of benefits, in the annual Call Letter (prior to 2020) and in bidding instructions. In addition, Chapter 4 of the Medicare Managed Care

Manual (MMCM) has contained long-standing polices regarding discriminatory cost sharing based on the requirements under paragraphs (f)(4) and (5).

We proposed to codify our current and longstanding practice and methodology for interpreting and applying the limits on MA cost sharing, with some modifications. Our cost sharing proposal as a whole, in combination with the MOOP limit proposal in section VI.A. of the February 2020 proposed rule, aimed to provide MA organizations incentives to offer plans with favorable benefit designs for beneficiaries. As noted in the February 2020 proposed rule, organizations must also comply with applicable Federal civil rights laws that prohibit discrimination, including those that prohibit discrimination on the basis of race, color, national origin, sex (including sexual orientation and gender identity), age, and disability, such as section 1557 of the Affordable Care Act, Title VI of the Civil Rights Act of 1964, section 504 of the Rehabilitation Act of 1973, and the Age Discrimination Act of 1975. None of the proposals in the February 2020 proposed rule limited application of such anti-discrimination requirements. Overall, our proposal aimed to clarify how we use the most relevant and appropriate information to determine whether specific cost sharing is discriminatory and to calculate standards and thresholds above which we believe cost sharing is discriminatory. We shared our intent to communicate, similar to our current practice prior to bid submission, how we apply the proposed methodologies each year, such as through HPMS memoranda, as appropriate. We solicited comment on the following cost sharing proposals:

- Codifying a long-standing interpretation of the current anti-discrimination provision of section 1852(b)(1) that payment of less than 50 percent of the total MA plan financial liability discriminates against enrollees who need those services;
- Establishing a range of cost sharing limits for basic benefits furnished on an in-network basis based on the MOOP type established by the MA plan;
- Codifying the methodology used to calculate the limits for MA cost sharing for inpatient hospital acute and psychiatric services and incorporate ESRD costs into that

methodology;

- Updating the cost sharing limits for emergency and post-stabilization services and codifying a new rule for cost sharing limits for urgently needed services;
- Codifying and adding specific benefits for which MA plans may not charge enrollees higher cost sharing than is charged under original Medicare; and
- Codifying our existing policy regarding the specific benefit categories for which an MA plan must not exceed the cost sharing in original Medicare on a PMPM actuarially equivalent basis.

The changes to the cost sharing proposals we are finalizing in this FC range from minor edits, corrections, and clarifications to substantive modifications based on the comments received, operational considerations (such as, changes stemming from the timing of this FC), and improvements to the methodology. CMS's goal in finalizing the cost sharing proposals as described in this FC is to adopt standards and require compliance that further antidiscriminatory requirements (such as, by supporting equitable access to plans for beneficiaries with high health needs). A complete discussion of changes from the February 2020 proposed rule is available in section II.B. of this FC.

3. Summary of Costs and Benefits

Provision	Description	Primary Impact to MA Organizations, Enrollees, and Medicare Trust Fund (as applicable)
a. Maximum Out-of-Pocket (MOOP) Limits for Medicare Parts A and B Services (§§ 422.100 and 422.101)	CMS is finalizing policies (with some modifications and changes in implementation schedule) to: Codify the approximate Medicare FFS percentiles which are used to determine the mandatory and lower MOOP limits and calculate an intermediate MOOP limit representing the numeric midpoint between mandatory and lower limits. Incorporate costs related to beneficiaries with diagnoses of End-Stage Renal Disease (ESRD) into the methodology to calculate MOOP limits, because of the eligibility changes permitting broader enrollment in MA plans by beneficiaries with ESRD beginning in contract year 2021. Establish guardrails to mitigate disruptive changes in MOOP limits, including a cap on how much MOOP limits can increase from year to year. Adopt a provision regarding the release of annual guidance that identifies the MOOP and cost sharing limits and includes a description of how the regulation standards are applied. Clarify the use of generally accepted actuarial principles and practices for the projections and calculations used for the MOOP and cost sharing limits, including specific principles for how discretion in applying the actuarial standards will be used. Codify additional standards for combined/catastrophic MOOP limits, updating the ESRD cost transition based on comments and operational considerations stemming from the timing of this FC, adopting a simpler methodology than proposed to protect against disruptive annual changes in MOOP limits, clarifying the methodology CMS uses to calculate MOOP limits, and making additional clarifications. Sets the specific MOOP limits for contract year 2023 using the methodology and standards in §§ 422.100(f) and 422.101(d) in addition to adopting the rules for 2024 and subsequent years.	While individual or groups of beneficiaries using specific categories of services and items may have possibly significant savings or losses, there is no aggregate cost impact to either the government or MA organizations for two reasons: (1) there is a statutory requirement for submitted bids to be actuarially equivalent to original Medicare, implying that plans can shift costs, but not create additional costs (that is, even if submitted bids proposed shifts in cost sharing of particular service categories there will be no dollar impact in the aggregate); and (2) to the extent that provisions of this FC codify existing practice, we are certain of no cost impact because of the annual review of bids which confirms compliance.

Provision	Description	Primary Impact to MA
		Organizations, Enrollees, and
b. Service Category Cost Sharing Limits for Medicare Parts A and B Services and per Member per Month Actuarial Equivalence Cost Sharing (§§ 422.100 and 422.113)	CMS is finalizing policies (with some modifications and changes in implementation schedule) to: Codify the long-standing CMS policy that enrollee cost sharing greater than 50 percent of the total MA plan financial liability or Medicare FFS allowed amount in the plan service area for Parts A and B benefits is discriminatory. Set cost sharing limits for seven inpatient length of stay scenarios based on a percentage of estimated Medicare FFS cost sharing projected for the applicable contract year, including applying a transition schedule to incorporate costs incurred by beneficiaries with diagnoses of ESRD. Revise long-standing CMS policy that limits cost sharing for several professional services to be no greater than 50 percent of the plan's financial liability regardless of the type of MOOP limit by updating the standard to: 50 percent coinsurance for lower MOOP limit, 40 percent for intermediate MOOP limit, and 30 percent for mandatory MOOP limit. Increase the maximum per visit cost sharing for emergency care (\$90 to \$115 for a mandatory MOOP and \$120 to \$150 for a lower MOOP) based on 15 and 20 percent of the Medicare FFS median allowed amount for emergency services and establish a \$130 cost sharing limit for an intermediate MOOP limit. Adopt a requirement that MA plans must use cost sharing that does not exceed cost sharing in original Medicare for home health services, durable medical equipment for plans with a mandatory MOOP amount, and Part B drugs other than chemotherapy administration services, skilled nursing care (that is, SNF), and renal dialysis services. Codify CMS's long-standing policy of evaluating cost sharing limits on a PMPM actuarially equivalent basis for the following service categories: Inpatient hospital, SNF, DME, and Part B drugs. Transition the contract year 2022 cost sharing standards for professional service categories: Inpatient hospital, SNF, DME, and Part B drugs. Clarify current policies for cost sharing limits for emergency services, and benefits for which cost sharing l	applicable) While individual or groups of beneficiaries using specific categories of services and items may have possibly significant savings or losses, there is no aggregate cost impact to either the government or MA organizations for two reasons: (1) there is a statutory requirement for submitted bids to be actuarially equivalent to original Medicare, implying that plans can shift costs, but not create additional costs (that is, even if submitted bids proposed shifts in cost sharing of particular service categories there will be no dollar impact in the aggregate); and (2) to the extent that provisions of this FC codify existing practice, we are certain of no cost impact because of the annual review of bids which confirms compliance.
Cost Sharing Limits for Medicare Parts A and B Services and per Member per Month Actuarial Equivalence Cost Sharing (§§	changes in implementation schedule) to: Codify the long-standing CMS policy that enrollee cost sharing greater than 50 percent of the total MA plan financial liability or Medicare FFS allowed amount in the plan service area for Parts A and B benefits is discriminatory. Set cost sharing limits for seven inpatient length of stay scenarios based on a percentage of estimated Medicare FFS cost sharing projected for the applicable contract year, including applying a transition schedule to incorporate costs incurred by beneficiaries with diagnoses of ESRD. Revise long-standing CMS policy that limits cost sharing for several professional services to be no greater than 50 percent of the plan's financial liability regardless of the type of MOOP limit by updating the standard to: 50 percent coinsurance for lower MOOP limit, 40 percent for intermediate MOOP limit, and 30 percent for mandatory MOOP limit. Increase the maximum per visit cost sharing for emergency care (\$90 to \$115 for a mandatory MOOP and \$120 to \$150 for a lower MOOP) based on 15 and 20 percent of the Medicare FFS median allowed amount for emergency services and establish a \$130 cost sharing limit for an intermediate MOOP limit. Adopt a requirement that MA plans must use cost sharing that does not exceed cost sharing in original Medicare for home health services, durable medical equipment for plans with a mandatory MOOP amount, and Part B drugs other than chemotherapy, in addition to the current limit for chemotherapy administration services, skilled nursing care (that is, SNF), and renal dialysis services. Codify CMS's long-standing policy of evaluating cost	Medicare Trust Fund (as applicable) While individual or groups of beneficiaries using specific categories of services and items may have possibly significant savings or losses, there is no aggregate cost impact to either the government or MA organizations for two reasons: (1) there is a statutory requirement for submitted bids to be actuarially equivalent to original Medicare, implying that plans can shift costs, but not create additional costs (that is, even if submitted bids proposed shifts in cost sharing of particular service categories there will be no dollar impact in the aggregate); and (2) to the extent that provisions of this FC codify existing practice, we are certain of no cost impact because of the annual review of bids which
	sharing limits on a PMPM actuarially equivalent basis for the following service categories: Inpatient hospital, SNF, DME, and Part B drugs. • Transition the contract year 2022 cost sharing standards for professional service categories, emergency services, and	
	Medicare to the cost sharing limits established using the methodology adopted by this FC. • Clarify current policies for cost sharing, such as scope of the	
	not including post-stabilization inpatient acute care services for purposes of setting the cost sharing limits for emergency	
	using the methodology and standards in §§ 422.100(f) and (j)	
	subsequent years.	

B. Background

We received approximately 44 timely pieces of correspondence containing multiple comments for the provisions implemented in this FC from the February 2020 proposed rule.

Comments were submitted by health plans, provider associations, beneficiary and other advocacy organizations, and pharmaceutical companies.

We are finalizing the policies from the February 2020 proposed rule in more than one final rule. The first final rule titled "Medicare Program; Contract Year 2021 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, and Medicare Cost Plan Program" appeared in the **Federal Register** on June 2, 2020 (85 FR 33796) (June 2020 final rule), and contained a subset of regulatory changes that impacted MA organizations and Part D sponsors more immediately. The second final rule titled "Medicare and Medicaid Programs; Contract Year 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly" appeared in the **Federal Register** on January 19, 2021 (86 FR 5864) (January 2021 final rule), and contained the majority of the remaining provisions from the February 2020 proposed rule. This FC addresses the two remaining provisions from the February 2020 proposed rule.

The changes to the proposals we are finalizing in this FC range from minor edits, reorganizations, corrections, and clarifications to substantive modifications based on the comments received, operational considerations (such as, changes stemming from the timing of this FC), and improvements to the methodology. CMS's goal in finalizing the cost sharing proposals as described in this FC is to adopt standards and require compliance that further antidiscriminatory requirements (such as, by supporting equitable access to plans for beneficiaries with high health needs). Summaries of the public comments received and our responses to those public comments are set forth in the various sections of this FC under the appropriate headings. We also note that some of the public comments received for the provisions implemented in this FC were outside of the scope of the February 2020 proposed rule. Summaries of the out-of-scope public comments made in relation to the provisions in this FC are provided in the various sections of this FC under the appropriate headings.

The Code of Federal Regulations (CFR) will be updated consistent with the respective effective date of each provision. Because CMS is finalizing these regulations as applicable for the contract year and coverage beginning January 1, 2023, the requirements in this FC will apply to MA bid submissions occurring in calendar year 2022 for contracts effective January 1, 2023.

II. Codifying Existing Part C and D Program Policy

A. Maximum Out-of-Pocket (MOOP) Limits for Medicare Parts A and B Services (§§ 422.100 and 422.101)

Section 1852(b)(1) of the Act prohibits discrimination by MA organizations on the basis of health status-related factors and directs that CMS may not approve an MA plan if CMS determines that the design of the plan and its benefits are likely to substantially discourage enrollment by certain MA eligible individuals. Under the authority of sections 1852(b)(1)(A), 1856(b)(1), and 1857(e)(1) of the Act, CMS added §§ 422.100(f)(4) and (5) and 422.101(d)(2) and (3), effective for coverage in 2011, to require all MA plans (including employer group waiver plans (EGWPs) and special needs plans (SNPs)) to establish limits on enrollee out-of-pocket cost sharing for Parts A and B services that do not exceed the annual limits established by CMS (75 FR 19709 through 19711). MA EGWPs must follow all relevant MA regulations and guidance unless CMS has specifically waived a requirement under its section 1857(i) of the Act statutory authority. Section 1858(b)(2) of the Act requires a limit on in-network and out-of-pocket expenses for enrollees in Regional Preferred Provider Organization (RPPO) MA plans. In addition, MA Local PPO (LPPO) plans, under § 422.100(f)(5), and RPPO plans, under section 1858(b)(2) of the Act and § 422.101(d)(3), are required to have two maximum out-of-pocket (MOOP) limits (also called catastrophic limits) established by CMS annually, including (a) an in-network and (b) a total catastrophic (combined) limit that includes both in-network and out-of-network items and services covered under Parts A and B. Relying on the same authority, we proposed amendments to the regulations at §§ 422.100(f)(4) and (5) and 422.101(d)(2) and (3) to specify how these MOOP limits ("MOOP amounts" when referring to

the limit established by an MA plan) will be set for 2022 and subsequent years. In addition, our proposals considered statutory changes that are relevant to how CMS sets cost sharing limits.

Under our current policy, MA organizations are responsible for tracking out-of-pocket spending incurred by the enrollee (that is, cost sharing includes deductibles, coinsurance, and copayments, pursuant to § 422.2) and to alert enrollees and contracted providers when the MOOP limit is reached. Health Maintenance Organization-Point of Service (POS) plans may offer out-of-network benefits as supplemental benefits, but are not required to have these services contribute to the in-network MOOP limit or to a combined in- and out-of-network MOOP limit. Although the MOOP limits apply to Parts A and B benefits, an MA organization can apply the MOOP limit to supplemental benefits as well.

As discussed in the February 2020 proposed rule, CMS currently sets MOOP limits based on a beneficiary-level distribution of Parts A and B cost sharing for individuals enrolled in Medicare Fee-for-Service (FFS). The CMS Office of the Actuary (OACT) conducts an annual analysis to determine the MOOP limits using the most recent Medicare FFS data and by projecting cost sharing using trend factors, such as enrollment changes and enrollment shifts between MA and original Medicare. The OACT bases its projections on actual claims data for Parts A and B benefits from the National Claims History files. MOOP limits for 2020, 2021 and 2022 were set under the current regulation text at §§ 422.100(f)(4) and (5) and 422.101(d)(2) and (3) that authorizes CMS to set MOOP limits that strike a balance between limiting costs (meaning cost sharing and premiums) to enrollees and changes in benefits, with the goal of ensuring beneficiary access to affordable and sustainable benefit packages. The mandatory MOOP limit represents approximately the 95th percentile of projected Medicare FFS beneficiary out-of-pocket spending for the year to which the MOOP limit will apply. Stated differently, using the contract year 2020 MOOP limits as examples, 5 percent of Medicare FFS beneficiaries are expected to incur approximately \$6,700 or more in Parts A and B deductibles, copayments,

and coinsurance; the voluntary MOOP limit of \$3,400 represents approximately the 85th percentile of projected Medicare FFS out-of-pocket costs.

A strict application of the thresholds at the 95th and 85th percentile to set the MOOP limits, since adoption of the MOOP regulations for 2011, would have resulted in MOOP limits for MA LPPO and RPPO plans fluctuating from year-to-year. Therefore, CMS exercised discretion in order to maintain stable MOOP limits from year-to-year, when the established MOOP limits were approximately equal to the appropriate percentile. CMS took this approach in an effort to avoid enrollee confusion (which may result from annual MOOP fluctuations year over year), allow MA plans to provide stable benefit packages year over year, and not discourage MA organizations from adopting the lower voluntary MOOP limit because of year to year fluctuations in the MOOP limits set by CMS.

MA plans may establish MOOP amounts that are lower than the CMS-established maximum limits. As discussed in the February 2020 proposed rule, for 2020, we considered any MOOP amount within the \$0 - \$3,400 range as a voluntary MOOP limit and any MOOP amount within the \$3,401 - \$6,700 range as a mandatory MOOP limit. These amounts were updated to \$0 - \$3,450 for the voluntary MOOP and \$3,451 - \$7,550 for coverage in 2021 and 2022. The in-network MOOP limit dictates the combined MOOP range for PPOs (that is, PPOs are not permitted to offer a combined MOOP amount within the mandatory range, while having an in-network MOOP amount within the voluntary range). The combined MOOP limit for PPOs is calculated by multiplying the respective in-network MOOP limits by 1.5 for the relevant year and rounding, if necessary, similar to what we proposed at § 422.100(f)(4)(iii). For example, the voluntary combined MOOP limit for PPOs in contract year 2020 was calculated as \$3,400 x 1.5

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¹ See the HPMS memorandum titled "Final Contract Year 2021 Part C Benefits Review and Evaluation," issued April 8, 2020, for information on MOOP and cost sharing limits for contract year 2021 and the HPMS memorandum titled "Final Contract Year 2022 Part C Benefits Review and Evaluation," issued May 20, 2021, for information on MOOP and cost sharing limits for contract year 2022.

² CMS. "Benefits Policy and Operations Guidance Regarding Bid Submissions; Duplicative and Low Enrollment Plans; Cost Sharing Standards; General Benefits Policy Issues; and Plan Benefits Package (PBP) Reminders for Contract Year (CY) 2011" (2010). Retrieved from https://www.cms.gov/Medicare/Health-Plans/HealthPlans GenInfo/downloads/dfb_policymemo041610final.pdf

= \$5,100 (that is, an MA plan that establishes a dollar limit within the \$0 - \$5,100 range is using a lower, voluntary combined MOOP limit). Similarly, the mandatory combined MOOP limit for PPOs in contract year 2020 was calculated as $$6,700 \times 1.5 = $10,050$, rounded down to the nearest \$100 (\$10,000) and MA plans that establish a dollar amount within the \$5,101 - \$10,000 range are using a mandatory combined MOOP limit.

As noted in the February 2020 proposed rule, CMS affords greater flexibility in establishing Parts A and B cost sharing to MA plans that adopt a lower, voluntary MOOP amount (including PPO plans with a combined MOOP limit in the voluntary range) than is available to plans that adopt the higher, mandatory MOOP amount. The percentage of MA plans (excluding employer, dual eligible special needs plans (D-SNPs), and Medicare Medical Savings Accounts plans (MSAs)) offering a voluntary MOOP limit and the proportion of total enrollees in a plan with a voluntary MOOP limit (at or below \$3,400) have decreased considerably from contract year 2011 to contract year 2020. Based on plan data from March 2021, this trend has continued through contract year 2021 with approximately 18.5 percent of plans (21.5 percent of enrollees) having an in-network MOOP amount within the range of the prior voluntary MOOP limit (at or below \$3,400), as shown in Table 1. This percentage access to the voluntary MOOP increases to approximately 23.3 percent of plans (24.8 percent of enrollees) for contract year 2021 after taking into consideration the increase to the voluntary MOOP limit for that year (at or below \$3,450).

TABLE 1: PERCENT ACCESS TO MA PLANS (EXCLUDING EMPLOYER, D-SNP, AND MSA PLANS) WITH VOLUNTARY/LOWER MOOP AMOUNTS FROM 2011 TO 2021 BASED ON MARCH 2021 PLAN DATA

Year ¹	Percent of MA plans with Voluntary/Lower MOOP Amounts	Percent of Enrollees in an MA Plan with a Voluntary/Lower MOOP Amount
2011	51.9%	51.2%
2012	48.4%	48.9%
2013	46.4%	43.8%
2014	38.0%	32.3%
2015	31.0%	25.6%
2016	25.2%	22.3%
2017	20.6%	20.7%
2018	20.1%	22.8%
2019	23.1%	26.0%
2020	24.7%	26.4%
2021 ²	23.3%	24.8%

¹The voluntary MOOP limit was \$3,400 for contract years 2011 through 2020; in contract year 2021 the amount increased to \$3,450 based on incorporating a percentage of the costs incurred by beneficiaries with diagnoses of ESRD.

CMS explained in the February 2020 proposed rule that we intend to continue using more than one MOOP limit with a goal of encouraging plan offerings that result in favorable benefit designs for beneficiaries. In addition, we explained that by codifying the methodology for how these MOOP limits will be set, we aimed to increase the level of transparency for the MOOP and cost sharing policies, and provide more stability and predictability to the MA program. For example, CMS expects implementing more than two levels of MOOP and cost sharing limits may increase beneficiary access to plans with MOOP limits below the mandatory MOOP limit or with lower cost sharing. CMS also discussed in the February 2020 proposed rule how section 17006 of the 21st Century Cures Act amended section 1851(a)(3) of the Act to allow Medicare eligible beneficiaries with diagnoses of end-stage renal disease (ESRD) to choose a MA plan for Medicare coverage starting January 1, 2021, without the restrictions on such enrollment that previously applied. Based on these prior enrollment restrictions, we explained how the data historically used by CMS to set the MOOP limits excluded the projected out-of-pocket spending

² These values reflect the percent access to a MOOP limit at or below \$3,450. Access to a MOOP limit at or below \$3,400 in 2021 is approximately 18.5 percent of plans (21.5 percent of enrollees).

for beneficiaries with diagnoses of ESRD, which we are referring to also in this FC as "ESRD costs," but that we believed the data used to set the MOOP limits for future years should align with this change in eligibility for the MA program. The February 2020 proposed rule also identified CMS authority for its proposal related to MOOP limits for MA plans as flowing from sections 1852(b)(1)(A), 1856(b)(1), 1857(e)(1), and 1858(b) of the Act. We proposed to codify our current practice, with some revisions, substantially revising and restructuring §§ 422.100(f)(4) and (5) and 422.101(d)(2) and (3) as described in the following subsections.

We are finalizing, for 2023 and subsequent years, the majority of our MOOP proposals with some changes. The changes include:

- Codifying explicit ranges used to determine if a MA plan's in-network (catastrophic) and combined (total catastrophic) MOOP limits are a mandatory, intermediate, or lower MOOP limit for purposes of § 422.100(f)(6) and (j) and §§ 422.101(d) and 422.113(b)(2)(v).
- Improving clarity in the regulations regarding how CMS will set the MOOP limits for 2023 and subsequent years, including how we will use actuarial principles and practices in making the projections required by the methodology to set MOOP limits and calculate the intermediate MOOP limit.
- Modifying the transition schedule for incorporating ESRD costs (that is, the out-of-pocket spending for beneficiaries with diagnoses of ESRD) into the methodology CMS uses to set MOOP limits.
- Simplifying the maximum threshold of the guardrails which was proposed to protect MA enrollees from potentially significant changes in out of pocket costs resulting from changes to the plan's MOOP amount (during and after the ESRD cost transition is completed).
- Removing the proposed requirement of a 3-year trend to update the MOOP limits, after the ESRD cost transition is completed, to avoid duplicating the OACT practice of trending years of data to project costs for an applicable year (which will ensure MOOP limits are updated to reflect changes in Medicare FFS costs in future years).

• Adopting explicit procedures for annually announcing the MOOP limits with a process for notice and comment by the public beginning for contract year 2024.

These changes are discussed in detail in section II.A.4. of this FC. This FC sets the specific MOOP limits for contract year 2023 using the methodology and standards in §§ 422.100(f) and 422.101(d) in addition to adopting the rules for 2024 and subsequent years.

1. Authorize Setting Up to Three MOOP Limits on Basic Benefits (§§ 422.100(f)(4) and (5) and § 422.101(d)(2) and (3))

CMS proposed to codify our current practices for setting MOOP limits with some revisions, including explicitly addressing authority to set up to three MOOP limits. In addition to the proposals specific to the methodology for setting the MOOP limits and how to incorporate ESRD costs into that methodology, we proposed specific rules for the MOOP limits. These proposals were to do all of the following:

- Use the term "basic benefits" instead of referring to Medicare Part A and B benefits in our proposed revisions to the regulations at §§ 422.100(f)(4) and (5) and § 422.101(d)(2) and (3) because the term "basic benefits" is now defined in § 422.100(c).
- Amend § 422.100(f)(4) to state the general rule that, except as provided in paragraph (f)(5), MA local plans must establish MOOP limits for basic benefits; as in the current regulation, proposed paragraph (f)(5) addressed how the MOOP limits apply to the out-of-network coverage provided by local PPO plans.
- Codify the rules for PPOs in establishing in-network and combined (or catastrophic) MOOP limits for basic benefits furnished in-network and out-of-network in §§ 422.100(f)(5) and 422.101(d)(2) and (d)(3).
- Add cross-references to codify the same limits under both § 422.100(f)(5) (for MA local PPOs) and § 422.101(d)(3) (for MA regional plans) for combined MOOP limits that apply to in-network and out-of-network cost sharing and to codify the same MOOP limit under

§ 422.100 (f)(4) (for MA local plans) and § 422.101(d)(2) (for in-network MA regional plans) to avoid repetitive regulation text.

- Codify in §§ 422.100(f)(4) and (5) and 422.101(d)(2) and (3) the responsibility MA organizations have to track enrolled beneficiaries' out-of-pocket spending and to alert enrollees and contracted providers when the MOOP limit is reached. This is implicit in how a MOOP limit works, but we believe codifying these responsibilities emphasizes for MA organizations that these requirements are integral to the administration of basic benefits.
- Amend § 422.100(f)(4) to authorize CMS, for 2022 and subsequent years, to set up to three MOOP limits using projections of beneficiary spending that are based on the most recent, complete Medicare FFS data, including the current mandatory and voluntary MOOP limits and a third, intermediate MOOP limit. CMS proposed to use these terms (lower, intermediate, and mandatory) in referencing MOOP limits instead of only "voluntary" and "mandatory" MOOP limits.
- Codify the current rule for using ranges to identify the type of MOOP amount an MA plan has established and applying that rule to the three proposed types of MOOP limits: the mandatory MOOP limit, the intermediate MOOP limit, and the lower MOOP limit in § 422.100(f)(4)(ii). Specifically, establishing that: (1) the mandatory MOOP limit is any dollar limit that is above the intermediate MOOP limit and at or below the mandatory MOOP limit threshold established each year; (2) the intermediate MOOP limit is any dollar limit that is above the lower MOOP limit and at or below the intermediate MOOP limit threshold established each year; and (3) the lower MOOP limit is any dollar limit that is between \$0.00 and up to and including the lower MOOP limit threshold established each year.
- Codify specific cost sharing limits and flexibilities tied to using the intermediate and lower (previously "voluntary") MOOP limits by MA plans (see section II.B. of this FC for the specific proposals).

2. Codify the Methodology for the Three MOOP Limits for 2022 and Subsequent Years (§ 422.100(f)(4))

CMS proposed to codify generally our current methodology for how we set MOOP limits with several revisions at § 422.100(f)(4) and to use cross-references in §§ 422.100(f)(5), 422.101(d)(2) and 422.101(d)(3) to establish how MOOP limits are set for local and regional plans. These proposals were to do all of the following:

- Amend § 422.100(f)(4) to impose general rules for setting the MOOP limits and codify the current practice of setting the MOOP limits based on a percentile of projected Medicare FFS beneficiary out-of-pocket spending, which would be developed based on the most recent, complete Medicare FFS data.
- Codify rounding each MOOP limit to the nearest whole \$50 increment, or the lower \$50 increment in cases where the MOOP limit is projected to be exactly in between two \$50 increments, in § 422.100(f)(4)(iii).
- Codify our current policy of setting the combined MOOP limits (that is, the MOOP limits that cover both in-network and out-of-network benefits) by multiplying the respective innetwork MOOP limits by 1.5 for the relevant year with rounding, if necessary, for MA regional plans in § 422.101(d)(3) and using a cross-reference to that rule for MA local PPOs in § 422.100(f)(5)(i).
- Establish the rules for setting the MOOP limits for contract years 2022, 2023, 2024, 2025, and subsequent years in § 422.100(f)(4)(iv), (v), and (vi). The proposal was, in effect, that the MOOP limits for contract year 2022 would be a recalibration of the MA MOOP limits by using a methodology adjusted from current practice. For contract year 2022, we proposed to set the MOOP limits as follows:
- The mandatory MOOP limit is set at the 95th percentile of projected Medicare FFS beneficiary out-of-pocket spending.

- The intermediate MOOP is set at the numeric midpoint of mandatory and lower MOOP limits.
- The lower MOOP limit is set at the 85th percentile of projected Medicare FFS beneficiary out-of-pocket spending.

These MOOP limits would be set subject to the rounding rules at § 422.100(f)(4)(iii). CMS proposed to use projections for the applicable contract year of out-of-pocket expenditures for Medicare FFS beneficiaries that are based on the most recent, complete Medicare FFS data that incorporates a percentage of the costs incurred by beneficiaries with diagnoses of ESRD (called "ESRD costs" in this FC), using the ESRD cost transition schedule proposed in paragraph (f)(4)(vii). In the following subsection, II.A.3. of this FC, we summarize that transition schedule and the data we proposed to use for setting MOOP limits.

For future contract years, we proposed to set the MOOP limits using a methodology that considers the amount of change from the prior year's MOOP limits to minimize disruption and change for enrollees and plans. Our proposed methodology was designed to allow MA plans to provide stable benefit packages year over year by minimizing MOOP limit fluctuations unless a consistent pattern of increases or decreases in beneficiary out-of-pocket costs emerges over time. Again, we proposed that these MOOP limits would be set subject to the rounding rules and using projections based on the most recent, complete Medicare FFS data that incorporates a percentage of the costs incurred by beneficiaries with diagnoses of ESRD, using the transition schedule at § 422.100(f)(4)(vii). In addition, the proposed methodology for MOOP limits for years 2023 until the end of this transition schedule was designed to balance the incorporation of increased costs incurred by beneficiaries with diagnoses of ESRD into the Medicare FFS data projections used to calculate the MOOP limits with the goal of providing stability in the MOOP limits. For example, we proposed to delay the ESRD cost transition in years where the change in the MOOP limit might otherwise be too significant, specifically when projections for the upcoming contract year were outside the range of two percentiles above, or below, the applicable percentile of

Medicare FFS beneficiary out-of-pocket spending (including costs incurred by Medicare FFS beneficiaries with and without diagnoses of ESRD) from the prior year. Similarly, the proposed methodology for establishing MOOP limits for the years following the completion of the transition schedule was intended to provide stability in the MOOP limits by placing a cap on how much limits can increase from one year to the next when certain conditions are met.

To set the mandatory and lower MOOP limits for contract years 2023 and 2024 or, if later, until the end of the ESRD cost transition, we explained that under our proposal, CMS would--

- Review OACT projections of out-of-pocket spending for the applicable year that is based on updated Medicare FFS data, including all spending regardless of ESRD diagnoses;
- Compare the applicable year's projection of the 95th percentile and 85th percentile to the prior year's projections;
- Determine if the prior year's projections for the 95th percentile and 85th percentile are within a range, above or below, of two percentiles of the applicable percentile in that updated projection. For example, for the contract year 2023 mandatory MOOP limit, we would determine if the contract year 2022 95th percentile projection is between or equal to the 93rd and 97th percentiles of the projections for 2023 out-of-pocket expenditures;
- If the prior year's 95th and 85th percentile projections are between or equal to the two percentile ranges above or below, we would continue the ESRD cost transition schedule proposed at § 422.100(f)(4)(vii) for one or both of the MOOP limits;
- If one or both of the prior year's 95th and 85th percentile projections are not within the two percentile ranges above or below, we would increase or decrease one or both of the MOOP limits up to 10 percent of the prior year's MOOP limit annually until the MOOP limit reaches the projected 95th percentile for the applicable year, subject to the rounding rules as proposed at § 422.100 (f)(4)(iii). For example, if the dollar amount that needs to be transitioned represents 15 percent, then 10 percent would be addressed during the upcoming contract year, while any

remaining amount would be addressed during the following contract year (if applicable based on updated data projections from the OACT). During this period of time, we would delay implementation of the next step in the ESRD cost transition schedule proposed in paragraph (f)(4)(vii). The ESRD cost transition schedule would resume at the rate that was scheduled to occur once the prior year's projected 95th and 85th percentile remains within the range of two percentiles above or below the projected 95th percentile for the upcoming contract year. For example, for the contract year 2023 mandatory MOOP limit, if the 2023 projected 95th percentile corresponds to the projected 98th percentile for contract year 2022 out-of-pocket expenditures, we would set the contract year 2023 mandatory MOOP by increasing the contract year 2022 mandatory MOOP limit by up to 10 percent and rounding as proposed at paragraph (f)(4)(iii); and

• The intermediate MOOP limit would be set by either maintaining it as the prior year's intermediate MOOP limit (if the mandatory and lower MOOP limits are not changed), or updating it to the new numerical midpoint of the mandatory and lower MOOP limits, and rounding as proposed at § 422.100(f)(4)(iii).

We proposed regulation text to implement this process for setting the mandatory, intermediate, and lower MOOP limits at \S 422.100(f)(4)(v), with paragraphs (f)(4)(v)(A), (B) and (C) addressing the mandatory, intermediate, and lower MOOP limits respectively.

For contract year 2025 (or the year following the conclusion of the ESRD cost transition schedule proposed at § 422.100(f)(4)(vii)) and for subsequent years, we proposed to include in the methodology a process to consider trends that are consistent for 3 years. The proposed regulation text included "or following the ESRD cost transition" to clarify that the ESRD cost transition schedule may end in 2025 or extend longer due to how we proposed to handle any sudden increases or decreases in costs. For example, if for contract year 2023, the projected 95th percentile amount represents the 98th percentile from the prior year's (contract year 2022) projections, then we would only increase the MOOP limit for contract year 2023 by up to 10

percent of the prior year's MOOP amount and extend the ESRD cost transition schedule past 2025 by the number of years it takes until the upcoming year's projected 95th percentile amount was within two percentiles above or below the prior year's projection of the 95th percentile. We also proposed the methodology for the mandatory and lower MOOP limits for contract year 2025 or following the ESRD cost transition schedule. Specifically, CMS proposed that the prior year's corresponding MOOP limit is maintained for the upcoming contract year if: (1) the prior year's MOOP limit amount is within the range of two percentiles above or below the projected 95th or 85th percentile of Medicare FFS beneficiary out-of-pocket spending incurred by beneficiaries with and without diagnoses of ESRD; and (2) the projected 95th or 85th percentile did not increase or decrease for 3 consecutive years in a row. If the prior year's corresponding MOOP limit is not maintained because either (1) or (2) occur, CMS would increase or decrease the MOOP limit by up to 10 percent of the prior year's MOOP limit amount annually until the MOOP limit reaches the projected applicable percentile for the applicable year, based on the most recent, complete Medicare FFS data projections from the OACT. The intermediate MOOP limit would be set by either maintaining it as the prior year's intermediate MOOP limit (if the mandatory and lower MOOPs are not changed), or updating it to the new numerical midpoint of the mandatory and lower MOOP limits, and rounding as proposed in paragraph (f)(4)(iii). We proposed regulation text to implement this process for setting the mandatory, intermediate, and lower MOOP limits for contract year 2025 or following the data transition schedule and subsequent years at paragraph (f)(4)(vi), with paragraphs (f)(4)(vi)(A), (B), and (C) addressing the mandatory, intermediate, and lower MOOP limits respectively.

We explained that the principal goals of our proposal were to outline clearly the methodology for establishing the MOOP limits, to provide stability in MOOP limits and benefit packages, minimize fluctuations in the MOOP limits from year-to-year, and to minimize the potential for enrollee confusion that may result from fluctuations from year-to-year in the MOOP

limit. We solicited comment on whether the February 2020 proposed rule would accomplish those things.

3. Multiyear Transition of ESRD Costs into the Methodology for MOOP Limits (§ 422.100(f)(4))

Section 1851(a)(3) of the Act, as amended by section 17006 of the 21st Century Cures Act, permits Medicare beneficiaries with diagnoses of ESRD to enroll in MA plans beyond the previous enrollment limitations, beginning in contract year 2021. As discussed in the February 2020 proposed rule, CMS expected this change will result in Medicare beneficiaries with diagnoses of ESRD to begin transitioning to or choosing MA plans in greater numbers than previously. Specifically, the OACT expected ESRD enrollment in MA plans to increase by 83,000 beneficiaries as a result of the 21st Century Cures Act provision. The OACT assumed the increase would be phased in over 6 years, with half of those beneficiaries (41,500) enrolling during 2021. Based on actual 2021 enrollment data, the OACT continues to project that 83,000 beneficiaries with diagnoses of ESRD will enroll in the MA program over 6 years. We explained that the data we use to set the MOOP limits should also incorporate the out-of-pocket expenditures of beneficiaries with diagnoses of ESRD to reflect this statutory change.

For 2020 and prior years, CMS set MOOP limits using projected Medicare FFS beneficiary out-of-pocket spending for the year, based on a beneficiary-level distribution of Parts A and B cost sharing for individuals enrolled in Medicare FFS and excluding all costs for beneficiaries with ESRD. For example, for contract year 2020 MOOP limits, we used projected out-of-pocket costs for Medicare FFS beneficiaries (excluding out-of-pocket costs from beneficiaries with diagnoses of ESRD) prepared by the OACT, based on the most recent Medicare FFS data (from 2014 to 2018). We excluded the costs for individuals with diagnoses of ESRD because of the limits on when and how a Medicare beneficiary with diagnoses of ESRD could enroll in an MA plan under section 1851(a) of the Act. In the February 2020 proposed rule we stated that in contract year 2018, 0.6 percent of the MA enrollee population, or approximately

121,000 beneficiaries, have diagnoses of ESRD. This statistic was based on the statutory definition of ESRD and CMS data. Using more recent enrollment data, the number of beneficiaries enrolled in MA in contract year 2018 with diagnoses of ESRD is lower than previously stated, approximately 120,100 (which does not impact the 0.6 percent of the MA enrollee population figure)³. For 2021 and 2022, CMS set the voluntary and mandatory MOOP limits by applying the standard in §§ 422.100(f)(4) and (5) and 422.101(d)(2) and (3). Because of the expected changes in enrollment in MA plans by beneficiaries with diagnoses of ESRD beginning in 2021, we incorporated 40 percent of the ESRD cost differential (the difference between projected out-of-pocket costs for Medicare FFS beneficiaries with and without diagnoses of ESRD and only those without diagnoses of ESRD) for 2021 which increased both types of MOOP limits from 2020. These MOOP limits were maintained for contract year 2022.⁴

CMS developed the approach to conduct a multiyear transition of ESRD costs into the methodology for how CMS establishes MOOP limits with input from the OACT. CMS did not expect that those Medicare beneficiaries with diagnoses of ESRD that were expected to switch from FFS to MA would enroll in the MA program immediately after the enrollment limitations were lifted and as such, CMS did not propose to integrate all of the costs associated with all beneficiaries with diagnoses of ESRD within one contract year.

As part of developing the proposal, CMS looked at the impact of factoring in 100 percent of the costs of beneficiaries with ESRD into the data used to set MA MOOP limits. Using the most recent Medicare FFS data available at the time of the February 2020 proposed rule (2015 to 2019 data, with 2018 being the most heavily weighted), the OACT projected the out-of-pocket

Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2020.pdf.

³ The Fiscal Year President's Budgets may be accessed at https://www.govinfo.gov/app/collection/BUDGET/ and the annual Advance Notice and Rate Announcements may be accessed at https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents. In addition, see page 14 from the 2020 Rate Notice and Final Call Letter, retrieved from https://www.cms.gov/Medicare/Health-

⁴ See the HPMS memorandum titled "Final Contract Year 2021 Part C Benefits Review and Evaluation," issued April 8, 2020, for information on MOOP and cost sharing limits for contract year 2021. See the HPMS memorandum titled "Final Contract Year 2022 Part C Benefits Review and Evaluation," issued May 20, 2021, for information on MOOP and cost sharing limits for contract year 2022.

costs for Medicare FFS beneficiaries. Based on this data, we compared the 95th and 85th percentiles of the projected out-of-pocket costs for all Medicare FFS beneficiaries for the 2021 contract year to the \$7,175 and \$3,360 dollar amounts (calculated using the 95th and 85th percentiles of the projections without ESRD costs) to calculate the cost difference, which we consistently refer to as an ESRD cost differential. CMS calculated the \$999 95th percentile ESRD cost differential by comparing the \$7,175 to \$8,174 with related ESRD costs, a difference of \$999.

As discussed in the February 2020 proposed rule, our goal is to strike a balance between potential increases in plan costs and enrollee costs (meaning cost sharing and premiums) by scheduling adjustments to the MOOP limits (that is, adjustments to include data about the costs incurred by beneficiaries with diagnoses of ESRD into the data used to set the MOOP limits) to reflect a reasonable transition of ESRD beneficiaries into the MA program. Accordingly, our proposed revisions to the current methodology for setting MOOP limits included a scheduled transition for incorporating ESRD costs to allow MA organizations to plan for the change and mitigate sudden changes in MOOP limits, benefit designs, and premiums that could be disruptive to enrollees and MA organizations. To accomplish this, we proposed to do all of the following:

- Codify at § 422.100(f)(4)(vii) a multiyear transition schedule from our current practice of excluding all costs incurred by beneficiaries with diagnoses of ESRD to including all related costs into the Medicare FFS data that is used to set the MOOP limits.
- Add § 422.100(f)(4)(vii) to define the term "ESRD cost differential" to refer to the difference between: (1) projected out-of-pocket costs for beneficiaries using Medicare FFS data excluding the costs incurred by beneficiaries with ESRD diagnoses for contract year 2021 and (2) the projected out-of-pocket costs for all beneficiaries using Medicare FFS data (including the costs incurred by beneficiaries with ESRD diagnoses) for each year of the ESRD cost transition.
- Identify the specific dollar amounts in the regulation text defining the ESRD cost differential at § 422.100(f)(4)(vii), as \$7,175 for the 95th percentile and \$3,360 for the 85th

percentile based on the projected costs incurred by beneficiaries without ESRD diagnoses for the 2021 contract year.

- Add § 422.100(f)(4)(vii)(A), (f)(4)(vii)(B), and (f)(4)(vii)(C) to establish a specific schedule for factoring in an increasing percentage of the ESRD cost differential annually until 2024 or, if later, the final year of the transition and beyond.
- Begin the regulatory ESRD cost transition with the 2022 contract year, factoring in 60 percent of the ESRD cost differential and increasing that percentage by 20 percentage points for each successive year of the transition, as follows:
- -- For 2023 (or the next year of the transition), factor in 80 percent of the ESRD cost differential.
- -- For 2024 (or the final year of the transition), factor in 100 percent of the ESRD cost differential.

While we proposed to factor in the ESRD cost differential for contract year 2022 through contract year 2024, CMS initially started incorporating ESRD costs into the MOOP limits for contract year 2021. Specifically, CMS calculated the MOOP limits for contract year 2021, under the current regulations, using projections of Medicare FFS cost data from 2015 to 2019 for beneficiaries without diagnoses of ESRD. The OACT determined the Medicare FFS percentiles for 2021 by applying Medicare FFS cost sharing trends (consistent with the 2019 Medicare Trustees Report) to project contract year 2021 costs. CMS then added in 40 percent of the ESRD cost differential to the projected Medicare FFS percentiles. A more complete discussion on how CMS set MOOP limits for contract year 2021 is available in the HPMS memorandum titled "Final Contract Year 2021 Part C Benefits Review and Evaluation," issued April 8, 2020. In the February 2020 proposed rule, CMS also proposed a methodology to prevent excessive changes in the MOOP limit. Taking into consideration both the 2021 MOOP limits and our proposal for contract years 2022 through 2024, CMS's proposed policy would have effectively used a 4-year period to transition to full incorporation of ESRD costs.

CMS included in the February 2020 proposed rule two tables (Table 4, "Illustrative Example of In-Network MOOP Limits Based on Most Recent Medicare FFS Data Projections" and Table 5, "Illustrative Example of Combined MOOP Limits for LPPO and Catastrophic (MOOP) Limits for RPPO Plans Based on Most Recent Medicare FFS Data Projections") to show the potential impact of incorporating the out-of-pocket costs of Medicare FFS beneficiaries with diagnoses of ESRD into the methodology for the MOOP limits proposed at §§ 422.100(f)(4) and (5) and 422.101(d)(2) and (3) (85 FR 9077). These tables were developed to project 2021 costs using Medicare FFS data from 2015 - 2019, which was the most recent Medicare FFS data available at the time of the February 2020 proposed rule. In developing Tables 4 and 5 from the February 2020 proposed rule, we applied the proposed methodology, including not only the multiyear transition for incorporating the ESRD cost differential but also the rounding rules, and illustrated the ranges for the three MOOP limits. We explained that the tables were only illustrative MOOP limits for contract years 2022 through 2024 based on the most, recent complete Medicare FFS data at the time the February 2020 proposed rule was developed. As a result, we noted actual MOOP limits for these contract years may be different from the illustrative limits based on updated Medicare FFS data and projections. As part of our proposal, we explained that we would apply the methodology as codified and publish the resulting MOOP limits for each year on a timely basis, such as through an HPMS memorandum, with a description of how the regulation standard was applied, but we did not propose to codify the timeframe or a requirement for that publication.

In conclusion, we proposed to amend §§ 422.100(f)(4) and (5) and 422.101(d)(2) and (3) as described to allow plans to provide stable benefit packages year over year by minimizing MOOP limit fluctuations unless a consistent pattern of increases or decreases in costs emerges over time. We solicited comment on this approach in light of our goal of avoiding enrollee confusion and maintaining stable benefit packages. We also solicited comments whether our proposed regulation text adequately and clearly specified the methodology that would be used to

set the MOOP limits each year. We noted our intention to issue annual guidance applying these rules, in advance of the bid deadline so that MA organizations know and understand the MOOP limits for the upcoming year.

4. Comments Received and Responses for All MOOP Limit Provisions

We received feedback from 27 commenters on this proposal. The majority of comments were from health plans, provider associations, beneficiary and other advocacy organizations, and pharmaceutical companies. A summary of the comments (generally by issue) and our responses follows:

Comment: Several commenters supported CMS's proposals related to MOOP limits overall and some additional commenters supported codifying longstanding policies in regulation, including the Medicare FFS percentiles used to determine the MOOP limits. A few commenters that supported codifying longstanding policies in regulation noted that the standardization, transparency, and predictability of formal rulemaking provides program stability. A few other commenters specifically appreciated the additional transparency in how CMS sets the MOOP limits. A commenter was supportive of the MOOP limit proposal to codify the methodology CMS uses to set the MOOP limits and the addition of the third intermediate MOOP limit for the flexibility it would provide for MA organizations to innovate, improve available benefit offerings, and provide beneficiaries with affordable MA plans tailored to their unique healthcare needs and financial situation. Another commenter appreciated the opportunity to provide feedback to guide implementation processes.

Response: We thank commenters for their support. CMS believes codifying these flexibilities in regulation will encourage MA organizations to develop plan designs to take advantage of the flexibilities as well as provide transparency and stability for the MA program. In addition, we expect MA organizations will have a greater understanding about how the MOOP limits are calculated and be better prepared to anticipate changes in MOOP limits in future years as a result of this provision. As we discussed in the February 2020 proposed rule and

in more detail in our responses to comments, the goals of this rulemaking touch on several issues and we believe that this FC will result in positive outcomes for the MA program.

The changes to the proposals we are finalizing in this FC range from minor edits, reorganizations, corrections, and clarifications to substantive modifications based on the comments received, operational considerations (such as, changes stemming from the timing of this FC), and improvements to the methodology. Our goal in finalizing the cost sharing proposals as described in this FC is to adopt standards and require compliance that further antidiscriminatory requirements (such as, by supporting equitable access to plans for beneficiaries with high health needs). Because of the timing of this FC, operational considerations, and to help ensure that MA organizations have sufficient implementation time, the provisions in this FC will be applicable for coverage beginning January 1, 2023. This reflects a one-year delay from the proposed implementation schedule. When MA bids for contract year 2023 are submitted for review and approval by the statutory deadline (June 6, 2022 for contract year 2023), the regulations and final MOOP and cost sharing limits in this FC will be used to evaluate those bids for approval as well as applying to the coverage provided beginning January 1, 2023. Several modifications to the proposed regulation text (for example, changing a reference from January 1, 2022 to January 1, 2023 in § 422.100(f)(4)) are because of this change in the implementation of the MOOP provisions. Therefore, to avoid repetitive text in responses to comments in this section II.A. of this FC, we explain here that the proposed regulation text in §§ 422.100 and 422.101 was modified to change implementation by 1 year. Changes to the implementation of the proposed policies that are more nuanced are explained in detail (for example, section II.A.4.c. of this FC addresses the multi-year transition schedule of ESRD costs into MOOP limits). For the same reason, to avoid repetitive text, where there is no distinction made about the Medicare FFS data projections used, CMS means the data includes out-of-pocket costs from beneficiaries with and without diagnoses of ESRD. Specifically, the term "Medicare FFS data projections" is used as defined in § 422.100(f)(4)(i).

We take this opportunity to clarify, in addition to the discussion in the February 2020 proposed rule, which costs are tracked and accumulate toward the MOOP limit. As discussed in the final rule titled, "Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2012 and Other Changes" that appeared in the Federal Register on April 15, 2011 (76 FR 21431) (April 2011 final rule), the in-network (catastrophic) and combined (total catastrophic) MOOP limits consider only the enrollee's actual out-of-pocket spending for purposes of tracking out of pocket spending relative to its MOOP limit. This approach also applies to D-SNPs. Thus, for any D-SNP enrollee, MA plans are only required to count those amounts the individual enrollee is responsible for paying net of any State responsibility or exemption from cost sharing toward the MOOP limit rather than the cost sharing amounts for services the plan has established in its plan benefit package (PBP). (MA plans are permitted to count toward the MOOP any cost sharing that is exempted from collection because the enrollee is dually eligible for Medicare and Medicaid or that has been paid by Medicaid, but are not required to do so.) We did not propose in the February 2020 proposed rule to change the policy adopted in the April 2011 final rule regarding which cost sharing amounts must be counted toward the MOOP limit. We are finalizing the amended regulations at § 422.100(f)(4) and (f)(5) using the phrase "incurred by the enrollee" to be consistent with current § 422.101(d)(4), which refers to costs "incurred by" the enrollee in describing the MOOP limit. In the proposed rule titled, "Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs" that appeared in the Federal Register on January 12, 2022 (87 FR 1842) (January 2022 proposed rule), CMS is proposing that the MOOP limit in an MA plan (after which the plan pays 100 percent of MA costs for Part A and Part B services) be applied based on the accrual of all costsharing in the plan benefit, regardless of whether that cost sharing is paid by the beneficiary, Medicaid, other secondary insurance, or remains unpaid because of State limits on the amounts paid for Medicare cost-sharing and dually eligible individuals' exemption from Medicare costsharing. Throughout this FC and in the various regulations adopted here, we use "incurred by" in referring to out-of-pocket costs of an MA enrollee that are counted toward accumulation of the MA plan's MOOP amount to avoid suggesting this FC adopts an unproposed change in the policy from the April 2011 final rule or distinction in the data we use regarding out-of-pocket costs in the Medicare FFS program. In light of the January 2022 proposed rule, we note that the amendments regarding the phrase "incurred by the enrollee" described in this response may be subject to change if a final rule for the MOOP attainment proposal is published. However, other than in the specific cases related to an MA organization's obligation to track the MOOP limit for enrollees, the term is used in a more general sense that does not specifically incorporate this aspect of the current regulations for MOOP limits as applied to dually eligible individuals.

Under this FC, MA organizations are responsible for tracking out-of-pocket spending incurred by the enrollee, and must alert enrollees and contracted providers when the applicable MOOP amount is reached (for § 422.100(f)(4) the in-network MOOP; for paragraph (f)(5)(iii) the combined MOOP). In addition, we are not finalizing the regulations at § 422.101(d)(2)(ii) and (d)(3)(iii) as proposed (which substantively addressed the same requirement for the catastrophic (in-network) MOOP and the total catastrophic (combined) MOOP) to avoid repeating text that is in paragraph (d)(4). Existing § 422.101(d)(4) requires MA regional plans to track the deductible (if any) and catastrophic limits in paragraphs (d)(1) through (d)(3) based on incurred out-of-pocket beneficiary costs for original Medicare covered services and to notify members and health care providers when the deductible (if any) or a limit has been reached; we are not making any revisions to that specific provision. As finalized, the regulations at § 422.100(f)(4) and (f)(5)(iii) require MA organizations to track out-of-pocket spending incurred by the enrollee in a local MA plan and alert enrollees and contracted providers when the applicable MOOP amount (in-network, combined, catastrophic, or total catastrophic) is reached. This FC maintains the ability for D-SNPs to establish zero cost sharing for enrollees who are dually enrolled in both Medicare and Medicaid. For example, in a Zero-Dollar Cost Sharing D-

SNP, Medicare inpatient hospital stays and doctor visits are available at no cost to the enrollee.

A Medicare Non-Zero Dollar Cost Sharing D-SNP is a D-SNP under which the cost sharing for Medicare Part A and B services varies depending on the enrollee's category of Medicaid eligibility.

Comment: A few commenters requested that CMS educate beneficiaries with diagnoses of ESRD about their costs and plan choices in the MA program. Related to this topic, another commenter noted that dialysis providers may make special efforts to educate their patients about the option to enroll in a MA plan, so that the beneficiary may benefit from potential reductions in out-of-pocket costs because of the MOOP limit and the value of supplemental benefits in addition to the dialysis provider potentially being paid higher than Medicare FFS rates due to provider concentration and network adequacy requirements in the MA program.

Response: We agree with the commenters in that all beneficiaries should have access to the information they need to make informed decisions about what health plan best fits their needs. Enrollment of beneficiaries with diagnoses of ESRD in MA increased in the years prior to 2021 while the limitations on enrollment were in place. This suggests that this patient population is knowledgeable about Medicare plan choices. In addition, MA organizations, providers, and other stakeholders have been aware of the program change to allow (beyond the previous enrollment exceptions) Medicare beneficiaries with diagnoses of ESRD to enroll in MA beginning with contract year 2021 since the enactment of section 17006 of the 21st Century Cures Act in December 2016. CMS expects that MA organizations, providers, State Health Insurance Assistance Programs, and other stakeholders have and will continue to communicate information about MA plan options to all Medicare eligible beneficiaries, including those with diagnoses of ESRD. Section 422.111 requires that MA plans make materials available to existing and prospective enrollees, including provider networks, benefit coverage, and cost sharing. We believe that those requirements will also ensure that eligible beneficiaries, including those with diagnoses of ESRD, receive plan-level information they need to make an enrollment

election. In addition, CMS provides a Medicare & You handbook to all beneficiaries annually which includes information about MA plan options and eligibility (including for those with diagnoses of ESRD). We agree with the comment that dialysis and other specialty providers typically involved in caring for patients with diagnoses of ESRD may choose to make special efforts to educate their patients about the MA program. (We remind MA organizations that they and their downstream entities must comply with applicable marketing and communication regulations, including the limits on MA marketing activities with healthcare providers and in healthcare settings in § 422.2266.) CMS also expects beneficiaries with diagnoses of ESRD will evaluate all available health care plan options, including MA plans.

Comment: Several commenters had general concerns about beneficiaries with diagnoses of ESRD being discouraged from enrollment or having a lack of access to MA plans due to discriminatory benefit designs. For example, some commenters noted that enrollees with diagnoses of ESRD are more expensive and will reach the MOOP amount more quickly than enrollees without diagnoses ESRD, so MA organizations may have an incentive to discourage enrollment of beneficiaries with diagnoses of ESRD. In addition, commenters suggested MA plans may tier or use different out of pocket costs based on certain conditions, or limit benefits for ESRD enrollees compared to other enrollees. A commenter noted concerns about ESRD enrollees having adequate access to MA plan options based on the MOOP limits and network adequacy time and distance requirements (another provision from the February 2020 proposed rule).

Response: MA plans may not use higher MOOP amounts or limit benefits for enrollees with diagnoses of ESRD and CMS's review of bids will evaluate for and deny benefit packages that CMS determines are designed to discourage enrollment by beneficiaries with diagnoses of ESRD. As noted in the February 2020 proposed rule, section 1852(b)(1) of the Act prohibits discrimination by MA organizations on the basis of health status-related factors and directs that CMS may not approve an MA plan if CMS determines that the design of the plan and its benefits

are likely to substantially discourage enrollment by certain MA eligible individuals. In addition, as stated in section VI.B. of the February 2020 proposed rule (page 9079), MA organizations must comply with applicable Federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, sex (including sexual orientation and gender identity), age, disability, including section 1557 of the Affordable Care Act, title VI of the Civil Rights Act of 1964, section 504 of the Rehabilitation Act of 1973, and the Age Discrimination Act of 1975. The regulation at § 422.110 provides that an MA organization may not deny, limit, or condition the coverage or furnishing of benefits to individuals eligible to enroll in an MA plan offered by the organization on the basis of any factor that is related to health status. MA organizations discouraging or preventing enrollment in an MA plan by beneficiaries on the basis of their ESRD diagnoses after January 1, 2021, would be prohibited by § 422.110. CMS relies on the MA antidiscrimination provision, the agency's authority under section 1856(b) of the Act to adopt standards for MA organizations, and the agency's authority under section 1857(e) of the Act to add terms and conditions that are necessary, appropriate, and not inconsistent with the Medicare statute in setting the requirements under § 422.100(f)(4) and (5) that impose MOOP limits on local MA plans in alignment with the statutory catastrophic limits imposed on regional MA plans under section 1858(b) of the Act. We believe that requiring the inclusion of a MOOP limit in plan benefit design is necessary in order not to discourage enrollment by individuals who utilize higher than average levels of health care services (that is, in order for a plan not to be discriminatory in violation of section 1852(b)(1) of the Act). None of the provisions in this FC limit application of other anti-discrimination requirements.

As we discussed in the CY 2019 Call Letter⁵ and April 2018 final rule (83 FR 16440), the flexibility we have adopted for how MA plans must offer uniform benefits is premised on MA plans furnishing additional benefits to improve treatment and outcomes for a specific health

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⁵ Available at: https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents.

condition; that flexibility may not be used to lower or restrict benefits based on health status (83 FR 16480 through 16481). Therefore, the flexibility to offer additional supplemental benefits based on a connection with a particular health condition may not be used as a means to discourage enrollment by or discriminate against beneficiaries with diagnoses of ESRD. We encourage beneficiaries and other stakeholders to bring to our attention marketing and communications materials or other activities that may indicate that an MA organization is violating the anti-discrimination requirements applicable in the Medicare Advantage program by contacting 1-800-MEDICARE or by submitting a Medicare Complaint Form online⁶.

a. Authorize Setting Three MOOP Limits on Basic Benefits (§§ 422.100(f)(4) and (5) and 422.101(d)(2) and (3))

Comment: Several commenters supported CMS's proposal to add a third, intermediate MOOP limit. Commenters who supported the proposal noted that an intermediate MOOP limit will provide MA organizations the flexibility to innovate, improve benefit designs to offer high-value plan options to beneficiaries, and provide beneficiaries with affordable MA plans tailored for their unique healthcare needs and financial situation. A commenter stated this flexibility is increasingly important, as CMS has allowed MA organizations to develop specialized plans designed to address beneficiaries with chronic conditions. Another commenter was supportive and stated lower MOOP limits provide critical affordability protection for MA beneficiaries as actuarial firm modeling has shown that the voluntary MOOP limit provides substantial value to MA enrollees without driving higher member premiums. Several commenters supported CMS monitoring over time whether changes from the provisions in this FC result in beneficiaries having access to plan offerings with MOOP limits below the mandatory MOOP limit or lower

⁶ The online Medicare Compliant Form may be accessed and submitted at: https://www.medicare.gov/medicarecomplaintform/home.aspx.

⁷ Julia M. Friedman, Brett L. Swanson, Mary G Yeh, and Jordan Cates, Milliman Inc., "State of the 2020 Medicare Advantage industry: As strong as ever." February 14, 2020 https://at.milliman.com/en/insight/state-of-the-2020-medicare-advantage-industry-as-strong-as-ever.

cost sharing. A commenter noted that this monitoring is critically important to ensuring that CMS can effectively enforce the anti-discrimination provision of the statute.

Response: We appreciate the support. By implementing more than two types of MOOP limits and providing increased flexibility in the cost sharing limits for MA organizations with a lower MOOP amount, we expect to encourage MA plan offerings with favorable benefit designs so that beneficiaries can choose plans that meet their needs. CMS compared the percentage of contract year 2021 plans with MOOP amounts within the final dollar range of each MOOP type for contract year 2023 (as calculated using the methodology set through this FC) to determine the proportion of plans that established a MOOP amount that would be considered one of the three MOOP types we are finalizing for use beginning in contract year 2023. Based on plan data from March 2021 (excluding employer, D-SNPs, and MSA plans), the percentage of contract year 2021 plans (and enrollees) with an in-network MOOP amount within the final dollar range of each MOOP type for contract year 2023 (as shown in Table 5, which incorporates ESRD costs as discussed in section II.A.4.c. of this FC) is approximately:

- 24.9 percent of plans (25.8 percent of enrollees) have an in-network MOOP amount between \$0 and \$3,650 (the contract year 2023 lower MOOP limit);
- 36.9 percent of plans (41.7 percent of enrollees) have an in-network MOOP amount between \$3,651 and \$6,000 (the contract year 2023 intermediate MOOP limit); and
- 38.2 percent of plans (32.6 percent of enrollees) have an in-network MOOP amount between \$6,001 (the lowest range amount for the contract year 2023 mandatory MOOP limit) and \$7,550 (the highest allowable contract year 2021 mandatory MOOP amount).

 This distribution shows that the smallest proportion of contract year 2021 plans established a MOOP amount that would qualify for a lower MOOP type in contract year 2023 (see Table 5 for the final contract year 2023 MOOP limits). A contributing factor to this distribution may be how most cost sharing standards for professional services have been historically set at the same amount regardless of the MOOP type (mandatory or lower, previously "voluntary" MOOP limit)

established by the MA plan. In section VI.B. of the February 2020 proposed rule, we proposed differentiating cost sharing limits for highly utilized services (for example, primary care physician and physician specialist PBP service categories) and various other cost sharing services categories by the MOOP type, with lower MOOP limits receiving the most cost sharing flexibility. By establishing the maximum permitted cost sharing limit at different amounts (that is, by using a range of differentiated cost sharing limits for most services) across the three MOOP types, this FC is expected to promote greater differences between plans and provide MA organizations with meaningful cost sharing flexibilities if they choose to use the lower MOOP limits in their benefit design.

As discussed further in section II.B. of this FC, plan designs with mandatory MOOP types will have less flexibility in cost sharing and therefore less ability to use cost sharing as a means to incentivize enrollee behavior and manage medical costs beginning in contract year 2023. For example, MA organizations that establish a mandatory MOOP type for contract year 2026 will be subject to a 30 percent coinsurance limit for certain professional services and those that establish an intermediate MOOP type will be subject to a 40 percent coinsurance limit (as finalized in section II.B. of this FC). As discussed in the February 2020 proposed rule, the 30 percent coinsurance amount is most closely related to the cost sharing limit amounts stated in the CY 2020 Call Letter. Stated another way, we expect MA plans that establish a mandatory MOOP type will have lower or comparable copayment amounts when compared to existing benefit packages because the copayment limits set by CMS in past years for MA plans were, based on 2015 through 2019 Medicare FFS data projections available at the time of the February 2020 proposed rule, close to the 30 percent limit being set in this FC for several professional standards. In addition, by offering the intermediate MOOP type, we will be providing a midlevel MOOP option which is currently projected (for contract year 2023) to represent approximately 37 percent of plan in-network MOOP amounts in contract year 2021. We expect the combination of the three MOOP types and proportional cost sharing flexibilities for each type will encourage plans to adopt lower or intermediate MOOP amounts and adopt cost sharing that is lower or comparable when compared to existing benefit packages. Without the intermediate MOOP type as an option, plans may be more likely to adopt higher MOOP limits as a result of being afforded less cost sharing flexibility. Plans could design their plan benefits in ways that also meet enrollee needs by focusing on other benefit features, such as, zero premium and supplemental benefits, rather than lower MOOP amounts.

CMS will monitor whether changes from this FC result in beneficiaries having access to MA plan offerings with lower or intermediate MOOP types and cost sharing that is lower or comparable when compared to existing benefit packages over time. Specifically, we will conduct these analyses annually and communicate concerns through the subregulatory process finalized at § 422.100(f)(7)(iii) and may consider whether changes are necessary in future rulemaking based on the results of these analyses.

Comment: A commenter had concerns about the potential beneficiary impact of having up to three MOOP limits for local and regional plans, such as the possibility of MA plans varying costs by beneficiary health status and tiering or targeting higher MOOP limits towards beneficiaries with diagnoses of ESRD. The commenter explained that if MA plans tiered or targeted higher MOOP limits that it would create a significant financial burden for beneficiaries with diagnoses of ESRD. In addition, the commenter believed these increased costs and benefit designs would discourage beneficiaries with diagnoses of ESRD and other chronic illnesses from enrolling in the MA program and ultimately result in the de facto elimination (or lack of access to meaningful coverage options) of MA plans, contrary to the intent of Congress. The commenter requested CMS clarify that MA plans may not target higher MOOP limits to only ESRD patients. This commenter also noted that the strong protections CMS applies for all other beneficiaries that prohibit discrimination on the basis of health status, should be applied fairly to beneficiaries with diagnoses of ESRD to prevent MA plans from discriminating against and discouraging beneficiaries with diagnoses of ESRD from enrolling in the MA program.

Response: We disagree that adding a third, intermediate MOOP limit will allow MA organizations to design plans that discriminate against beneficiaries with diagnoses of ESRD or other chronic conditions and discourage them from enrolling in the MA program. Nothing in the MOOP regulations, as proposed or finalized, permits an MA plan to have higher MOOP amounts for certain enrollees in the plan based on health status. Specifically, MA plans are not permitted to create tiered MOOP amounts based on chronic conditions, such as kidney failure or the need for dialysis services, and if a MA organization submitted a plan bid with tiered MOOP amounts based on chronic conditions, that benefit design would not be approved. MOOP limits are and must be applied uniformly to all plan enrollees and our proposal to add a third, intermediate MOOP limit did not change this requirement. In addition, MA plans are required to provide all medically necessary Medicare Parts A and B services to enrollees. We reiterate that the benefits for all enrollees in an MA plan must be uniform, subject to the waiver of uniformity that may be provided for an MA plan to target specific Special Supplemental Benefits for the Chronically Ill (SSBCI) under § 422.102(f) and how optional supplemental benefits are only provided for enrollees who elect to pay the extra premium for that coverage under § 422.101(c)(2). The ability to offer supplemental benefits that have a connection with a specific health condition is permitted only for reductions in cost sharing and additional benefits, not for decreasing benefits, and requires the supplemental benefit to be available to all similarly situated enrollees. Therefore, MOOP amounts are applied uniformly to all plan enrollees, while MA plans are allowed to offer different additional supplemental benefits, including additional reductions in cost sharing, for similarly situated individuals based on disease state or chronic health condition as part of a uniform benefit package. As proposed and finalized, the MOOP limits cannot be applied so that enrollees with diagnoses of ESRD have a higher or otherwise different MOOP amount. In addition, a more complete discussion about the statutes and regulations preventing MA plans from discriminating against beneficiaries with diagnoses of ESRD or other chronic

conditions is provided in section II.A.4. of this FC in response to other similar concerns about discrimination.

Finally, CMS will also continue evaluations based on enforcement of the current authority prohibiting plans from misleading beneficiaries in their marketing and communication materials and continue efforts to improve plan comparison tools and resources (for example, Medicare Plan Finder, Medicare & You, and 1–800–MEDICARE) in order to monitor whether plan communications give the impression that MOOP amounts are not applied uniformly for all enrollees. We encourage beneficiaries and other stakeholders to bring to our attention marketing and communication materials or other activities that may indicate that an MA organization is violating the anti-discrimination requirements applicable in the MA program, by contacting 1-800-MEDICARE or by submitting a Medicare Complaint Form online.⁸

<u>Comment:</u> A commenter believed a third MOOP limit may create choice confusion for new and existing enrollees when evaluating their plan options.

Response: We disagree that adding a third, intermediate MOOP limit will confuse beneficiaries when they are evaluating their plan options. CMS expects that all beneficiaries reviewing their plan options for the upcoming contract year will continue to consider a number of factors when choosing an MA plan, such as plan type, benefits, per-service cost sharing, provider network, and the MOOP amount. This information will continue to be available to beneficiaries in Medicare Plan Finder and MA plan communication materials. We also expect that MA organizations, providers, State Health Insurance Assistance Programs, and other stakeholders have and will continue to communicate information about MA plan options to all Medicare eligible beneficiaries. Although beneficiaries make their plan choice based on a number of factors, such as the MOOP amount and premium, they are typically not aware if the

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⁸ The online Medicare Compliant Form may be accessed and submitted at: https://www.medicare.gov/medicarecomplaintform/home.aspx.

plan's MOOP amount qualifies as a lower, intermediate, or mandatory MOOP limit based on MA regulations.

<u>Comment:</u> A commenter opposed a third, intermediate MOOP limit because it may result in higher MOOP limits for all MA beneficiaries.

Response: While there may be more variation in the MOOP amounts and cost sharing structures used by MA plans as a result of this FC, we believe that beneficiaries have the tools and resources to evaluate their expected out-of-pocket costs, compare cost sharing amounts charged by different MA plans, and determine whether a particular plan design would benefit them. For example, these comparisons may be assisted by using Medicare Plan Finder and communications materials. We expect the MOOP limit and cost sharing flexibilities finalized in this FC will allow MA organizations to design benefits that encourage positive enrollee decision-making about their health care needs and manage medical costs more effectively without producing plan options that are confusing for beneficiaries.

Under section 1854(a)(5)(C)(ii) of the Act, CMS is authorized to deny a plan bid if the bid proposes significant increases in enrollee costs or decrease in benefits from one plan year to the next. A plan's Total Beneficiary Cost (TBC) is the sum of the plan-specific Part B premium, plan premium, and estimated beneficiary out-of-pocket costs. CMS uses a standardized TBC evaluation for each bid to evaluate year over year changes when bids are submitted for the upcoming contract year. The TBC standard is applied at the plan level to ensure enrollees in each applicable plan are not subject to too significant an increase in costs or decrease in benefits from one plan year to the next. CMS has observed that MA organizations tend to reduce their profit margins, rather than substantially change their benefit package from one year to the next. We believe this tendency may be to ensure that a bid does not exceed the TBC threshold and also due to marketing and competitive forces; for example, an MA plan with fewer or less generous supplemental benefits, even for one year, may lose its enrollees to competing plans that offer these supplemental benefits. Thus, it may be advantageous for the MA organization to

temporarily reduce its margin, rather than reduce benefits. MA organizations have a range of cost sharing flexibilities for a few service categories now (such as, inpatient hospital acute and psychiatric length of stay scenarios) and typically do not establish the highest allowable cost sharing for the MOOP amount used by the MA plan. In fact, CMS has found that MA organizations typically offer benefits with lower cost sharing amounts than the maximum cost sharing limits for the vast majority of service categories we have permitted in past years (such as primary care physician). While we do not have definitive data, we believe this is due to multiple factors, including the principles and incentives inherent in managed care, effective negotiations between MA organizations and providers, and competition. Further, MA plan must, at a minimum, offer plan designs where the cost sharing for basic benefits is at least actuarially equivalent to the cost sharing in the original Medicare program. In addition, we expect beneficiary choice will continue to act as an incentive for MA organizations to offer favorable benefit designs. Considering these factors, CMS expects that differentiating cost sharing standards by the three MOOP types, and in some cases limiting the cost sharing flexibility for MA plans that establish a mandatory MOOP type, will encourage MA organizations to establish a lower MOOP type (that is, lower or intermediate) and/or lower cost sharing amounts for enrollees in order to maintain a competitive position in the market.

<u>Comment:</u> A commenter opposing the proposal was concerned that a third, intermediate MOOP limit would not provide a strong actuarial incentive for more MA plans to establish lower MOOP limits and that MA organizations may find it difficult to determine which MOOP limit offers the best value.

Response: We disagree with the comment that MA organizations may find it difficult to determine which MOOP amount offers the best value for their purposes as a result of this provision. CMS expects MA organizations have, and will use, business tools and actuarial resources to effectively structure benefit designs, including MOOP amounts.

Comment: A commenter opposing the proposal to add a third, intermediate MOOP limit suggested CMS encourage MA organizations to offer plans with lower MOOP limits through alternative means. The commenter suggested some alternative ways to incentivize MA plans to establish a voluntary, lower MOOP limit including that CMS: (1) raise the 85th percentile that determines the voluntary MOOP limit to the 87th or 88th percentile while maintaining the 95th percentile for the mandatory MOOP limit; or (2) provide higher ratings in the Part C and D Star Rating program for MA plans that establish the lower, voluntary MOOP limit. The commenter's rationale for increasing the percentile that determines the lower, voluntary MOOP limit was that MA plans could increase their cost sharing over time while the voluntary MOOP limit increases simultaneously, which would not encourage MA plans to switch to the mandatory MOOP limit.

Response: We appreciate the suggestions of other options to incentivize MA organizations to offer plans with lower MOOP amounts. While the commenter's suggestion to raise the percentile that we use to calculate the lower, voluntary MOOP limit might produce some incentive for MA plans to choose a lower MOOP type, it may also likely mean that enrollees face increased cost responsibility with the lower MOOP options than they would under our proposal and this FC. We believe maintaining the lower (previously "voluntary") MOOP limit at the 85th percentile is beneficial to enrollees and provides incentive to MA plans to offer lower MOOP amounts when the cost sharing flexibilities unique to each MOOP type are considered. The cost sharing provisions, addressed in section II.B. of this FC, provide incentives for MA organizations to offer lower MOOP amounts by permitting higher cost sharing when a lower (or intermediate) MOOP type is used. For example, CMS's longstanding policy has been to allow MA plans to establish up to 50 percent coinsurance for most in-network professional services (subject to exceptions, such as for inpatient hospital acute and psychiatric services, skilled nursing facility, chemotherapy administration including chemotherapy drugs and radiation therapy, and renal dialysis), regardless of the MOOP limit. In this FC, we limit this degree of flexibility of having up to 50 percent coinsurance for in-network professional services,

beginning in contract year 2023, to MA plans that establish lower MOOP amounts (40 percent coinsurance for intermediate MOOP amounts and 30 percent coinsurance for mandatory MOOP amounts after the transition period). The cost sharing flexibilities adopted in this rule apply to highly utilized services (for example, professional and inpatient hospital service categories) and, thus, afford the most flexibility to MA plans that have lower MOOP amounts. As a result, this flexibility will encourage MA organizations to establish MOOP amounts at or below the lower MOOP limit because they will have more flexibility in establishing cost sharing. Overall, we aim to prevent discriminatory benefit designs with the adoption of the methodologies and rules for setting MOOP and cost sharing limits and by capping the amount of financial responsibility the MA organization can transfer to enrollees. Limits on out-of-pocket costs prevent plan designs that deter or discourage enrollment by beneficiaries that are high utilizers of health care services or that have higher-cost medical needs.

In regard to a commenter's suggestion to provide additional star rating value for MA plans offering the lower voluntary MOOP amount, we believe this request is outside of the scope of our proposal. Our Star Ratings proposals did not include adding a quality measure or a quality rating methodological change tied to MOOP type and were finalized in section IV.D. of the January 2021 final rule (86 FR 5864).

We are finalizing our proposal for three MOOP limits. We take this opportunity to explain the use of terminology in this FC and the regulations; we use consistent language when referring to MOOP limits (calculated by CMS by applying the methodologies finalized here), MOOP amounts (established by MA organizations), and MOOP types (lower, intermediate, and mandatory) in §§ 422.100(f)(4) and (5) and 422.101(d)(2) and (3). We are also finalizing the regulations at §§ 422.100(f)(4) and (5) and 422.101(d)(2) and (3) with slight changes from the February 2020 proposed rule to be clearer that: (1) § 422.100(f)(4) applies to an in-network MOOP limit for local MA plans and, consistent with our current policy and practice, that innetwork MOOP limit applies to private fee-for-service (PFFS) plans; (2) § 422.100(f)(5) applies

to a combined MOOP limit (for basic benefits that are provided in-network and out-of-network) for MA local PPO plans; (3) § 422.101(d)(2) applies to a catastrophic limit (in-network MOOP limit) for regional MA plans; and (4) § 422.101(d)(3) applies to a total catastrophic limit (combined MOOP) for regional MA plans. In addition, we made edits throughout these provisions to ensure clarity and consistency in referencing in-network, combined, catastrophic, and total catastrophic MOOP limits, amounts, or types. For example, in § 422.101(d)(3)(i) we clarify that the total catastrophic limit may not be used to increase the catastrophic limit described in paragraph (d)(2).

CMS is finalizing § 422.100(f)(4) with a clearer statement that MA local plans must have an enrollee in-network MOOP amount for basic benefits that is no greater than the annual limit calculated by CMS using Medicare FFS data projections (as defined in paragraph (f)(4)(i)). We believe this change clarifies a point from the February 2020 proposed rule that HMO-POS plans may offer out-of-network benefits as supplemental benefits, but are not required to have these services contribute to the in-network MOOP amount or to a combined in- and out-of-network MOOP amount. Currently, and with the change proposed and finalized in this rule, paragraph (f)(5) requires MA local PPO plans to have a combined MOOP amount for basic benefits that are provided in network and out-of-network. This change compared to our proposed text for paragraph (f)(4) also improves the regulation text by making the requirement to not exceed MOOP limits calculated by CMS more definitive and transparent than the general reference to paragraph (f)(4) in the February 2020 proposed rule. In addition, we added a statement to paragraph (f)(4) to codify CMS's longstanding policy (since 2012) that PFFS plans must use the in-network MOOP limit for all covered basic benefits, regardless of whether the provider is contracted with the PFFS plan or whether the PFFS plan has a partial or full provider network. Specifically, PFFS plans have been subject to the in-network MOOP limits for in- and out-of-network benefits because of the complexities of their provider network designs and ability to use balance billing. We also modified paragraph (f)(4)(i) to clarify that CMS will calculate

three in-network MOOP limits. Additional changes to paragraph (f)(4)(i) (namely, defining a consistent term that describes the data CMS uses in the methodology to calculate MOOP limits and specifying the dollar ranges for each MOOP type) are discussed more completely in section II.A.4.b. of this FC.

We thank commenters for all of their input. In this FC, we are finalizing the proposed addition of a third, intermediate MOOP type at §§ 422.100(f)(4) and (f)(5) and 422.101(d)(2) and (d)(3). The three MOOP types will apply to MA local and regional plans and to in-network and, for PPO plans, out-of-network basic benefits. The methodology for calculating the MOOP limits, including that the calculations are subject to the rounding rules in paragraph (f)(4)(iii) and the ESRD cost transition schedule in paragraph (f)(4)(vii), is discussed in sections II.A.4.b. and c. of this FC. Among the modifications we are finalizing are a change in the scope of data used to calculate the MOOP and cost sharing limits (discussed in section II.A.4.b. of this FC) and a change in the transition schedule for the ESRD cost differential (discussed in section II.A.4.c. of this FC). Further, we are finalizing the addition of descriptive headings to $\S 422.100(f)(1) - (9)$ to orient the reader to the content in each paragraph. While we did not propose updates to paragraphs (f)(1) - (3), the addition of headings will improve the clarity of the regulations, does not change the substance of the regulations, and results in a consistent approach for paragraph (f). Paragraph (f)(6) and new paragraphs (f)(7) – (9) are discussed in detail in section II.B. of this FC.

b. Codify the Methodology for the Three MOOP Limits for 2023 and Subsequent Years (§ 422.100(f)(4))

<u>Comment</u>: A few commenters responded to the solicitation from the February 2020 proposed rule on whether a specific rule requiring CMS to issue subregulatory guidance applying the methodology in these regulations by a specific date each year should be codified. The commenters requested CMS provide guidance well in advance of the upcoming plan year that the MOOP limit changes are effective. A commenter requested CMS release annual guidance no

later than 60 days prior to the first Monday in April with a minimum 30-day comment period to align with the Advance Notice of Methodological Changes for the upcoming Calendar Year for Medicare Advantage Capitation Rates and Part C and Part D Payment Policies.

Response: CMS will apply the finalized regulations each year to calculate the MOOP limits for contract year 2023 and future years using the methodology adopted in this FC and the most recent Medicare FFS data projections. The final contract year 2023 MOOP limits in Table 5 are calculated using the methodology and formulas in § 422.100(f)(4). These calculations using contract year 2023 Medicare FFS data projections (based on 2017 to 2021 Medicare FFS data) are provided in Tables 2 through 4. We are adopting at § 422.100(f)(7)(iii) a provision regarding the release of annual subregulatory guidance beginning for contract year 2024. The guidance will identify the contract year MOOP limits that are set and calculated using the methodology and standards in §§ 422.100(f) and 422.101(d). This guidance may include a description of how CMS calculated the ESRD cost differential to set the MOOP limits. This annual guidance will be issued prior to bid submission to allow sufficient time for MA organizations to prepare and submit plan bids. We expect this date will typically be by the first Monday in April, which aligns with the deadline for the Rate Announcement for MA rates and the risk adjustment factors under section 1853(b) of the Act and § 422.312. Coordinating these MOOP and other cost sharing limit changes with the announcement of MA payment policies for the year is important to CMS and means that the final annual guidance of how the regulations we are adopting in this FC will be applied with updated data is unlikely to be issued prior to the first Monday in April. However, we are not adopting this date as a deadline for the final issuance of annual guidance specifying the MOOP limits and cost sharing standards as CMS may not always be able to meet this timeline as competing priorities, particularly those with statutory deadlines such as the Rate Announcement, may take precedence. For contract year 2024, we expect to issue the final MOOP limits and cost sharing standards sometime in April, 2023. As finalized in § 422.100(f)(7)(iii), CMS will provide a public notice and comment period on the projected

MOOP limits and cost sharing limits for the upcoming contract year unless a public comment period is impracticable, unnecessary, or contrary to the public interest. We believe these situations will be rare and intend to solicit comment annually, but believe that aligning the availability of prior notice and an opportunity to comment with rulemaking standards, which include authority to waive prior notice and a comment period when it is impracticable, unnecessary, or contrary to the public interest, is appropriate. To the extent necessary and appropriate, CMS may solicit and consider public comment on actuarial approaches before releasing the final MOOP limits and cost sharing standards as required in paragraph (f)(7)(iii). The exercise of actuarial judgment by the OACT may be a topic on which the public, or MA organizations, wish to comment when reviewing how CMS has applied the regulations adopted in this FC to calculate the benefit parameters for MA plans. As appropriate, we will consider such comments and may revise the decisions made in developing the projections and calculations of the MOOP and other cost sharing limits. In addition to using set departmental methods of posting guidance (for example, the HHS guidance repository), CMS may also release this annual subregulatory guidance through communication vehicles CMS has used in the past to deliver certain guidance, such as HPMS memoranda. We believe stakeholders are used to annual guidance for the MA program being released through these additional avenues and continuing this practice will encourage comment submissions as received in prior years.

We did not codify a deadline or a specific minimum time frame for the comment period on the MOOP and cost sharing standards for the upcoming contract year to ensure flexibility when necessary in future situations. As highlighted by the COVID-19 pandemic, maintaining a certain level of flexibility in regulation can be beneficial for the agency to better serve our stakeholders. For example, we may consider a comment period less than 30 days in the event of delays from external variables (such as, public health emergencies) when it is necessary in order to release final MOOP and cost sharing limits on a timeframe that is sufficient for MA

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⁹ Individuals and organizations may request placement on the HPMS listserv at https://hpms.cms.gov/app/ng/home/

organizations to prepare and submit plan bids. This approach will support the release of subregulatory guidance that addresses MOOP limits and cost sharing standards in advance of the upcoming plan year.

We are finalizing the proposal that the three MOOP types will be calculated using the 95th and 85th percentiles of projected Medicare FFS beneficiary out-of-pocket spending and the mid-point between those with the specific provisions as provided in § 422.100(f)(4). In addition, we are finalizing additional changes in the codification of the methodology that CMS uses to calculate MOOP limits in paragraph (f)(4). First, the ESRD cost transition (which was proposed in paragraph (f)(4)(vii)) is finalized in paragraph (f)(4)(vi) with changes from the proposal and we are finalizing the rules for calculating the in-network MOOP limits for 2023 in § 422.100(f)(4)(iv) and for 2024 and subsequent years in § 422.100(f)(4)(v) (as more completely addressed in section II.A.4.c. of this FC).

Second, we are not finalizing the term "complete" in various provisions that describe the data used to develop the cost projections that are the basis for calculating the MOOP limits to more accurately reflect current practice in calculating MOOP limits and cost sharing limits. The February 2020 proposed rule stated that the OACT uses the most recent, complete Medicare FFS data to project costs for the applicable year. Upon reflection, CMS realizes that the word "complete" may be subject to different interpretations. For example, "complete" could be interpreted as meaning that the data for that year being used to project costs is missing no information or that only one year of data would be used by the OACT to project costs. To ensure clarity in the regulation text on this point, we are removing the reference of "complete" and explaining here how the OACT approaches developing the projections to be used in calculating cost sharing limits. In developing the projections that CMS uses to determine cost sharing limits, the OACT uses several years of Medicare data (generally 99 percent complete) that apply trend factors (consistent with the most recent Medicare Trustees Report). The trend factors give the most weight to the more recent calendar years of data. Projections are then modified using

actuarial judgement. This is considered an actuarially acceptable approach in determining and projecting Medicare FFS percentiles and is consistent with longstanding policy. As a result, we are updating the references to the data CMS uses to calculate MOOP and cost sharing limits throughout the regulations at §§ 422.100(f) and (j) and 422.101(d). Specifically, in paragraph (f)(4)(i) we are defining the term, "Medicare FFS data projections" as meaning the projections of beneficiary out-of-pocket costs for the applicable contract year, based on recent Medicare FFS data, including data for beneficiaries with and without diagnoses of ESRD, that are consistent with generally accepted actuarial principles and practices as outlined in paragraph (f)(7)(i) (discussed subsequently in this response). The Medicare FFS data and resulting Medicare FFS data projections necessarily include cost and utilization data associated with the projected out-of-pocket costs. As defined and used throughout the regulations, the term "Medicare FFS data projections" concisely and consistently describes the data CMS uses to calculate MOOP and cost sharing limits. In addition, we believe using the term "Medicare FFS data projections" in describing the data is consistent with past practice and our intent for this aspect of the methodology (that is, data are from calendar years but the data are not fully complete, data from more than one calendar year may be used, trend factors are used, and projections are made to the contract year for which the MOOP limits are set). Based on the definition and how we have used the term, the Medicare FFS data projections reflect full incorporation of the ESRD cost differential.

Third, we are finalizing the substance of proposed § 422.100(f)(4)(ii)(A) through (C) in paragraphs (f)(4)(i)(A) through (C) with clarification. Specifically, we are clarifying in paragraphs (f)(4)(i)(A) and (B), consistent with Table 4 (Illustrative Example of In-Network MOOP Limits Based on Most Recent Medicare FFS Data Projections) in the February 2020 proposed rule, that the ranges determining in a plan's MOOP amount is considered a mandatory or intermediate MOOP type are as follows:

- Mandatory MOOP limit: One dollar above the intermediate MOOP limit and up to and including the mandatory MOOP limit.
- Intermediate MOOP limit: One dollar above the lower MOOP limit and up to and including the intermediate MOOP limit.

We are finalizing the description of the range for the lower MOOP limit in paragraph (f)(4)(i)(C) as proposed (in paragraph (f)(4)(ii)(C)) as we believe the proposed regulation text is sufficiently clear.

Next, we are finalizing § 422.100(f)(4)(ii) with a more complete list of the regulations which use the terms "mandatory MOOP limit," "intermediate MOOP limit," and "lower MOOP limit." These terms encompass a MOOP amount that varies from the specific highest allowable dollar figure announced by CMS for each MOOP type when the plan's MOOP amount is within the ranges specified in § 422.100(f)(4)(i)(A) through (C). We proposed to refer to paragraphs (f)(6) and (j) of § 422.100, but are finalizing references to paragraphs (f) and (j) of § 422.100, \$ 422.101(d), and § 422.113(b)(2)(v). This change better reflects the cost sharing requirements finalized in section II.B. of this FC. Referring to § 422.101(d) is consistent with how the types of in-network MOOP limits referenced in §422.100(f)(4)(i)(A), (B), and (C) will be used, beginning for contract year 2023, to calculate the catastrophic and total catastrophic (combined MOOP) limits that apply to regional plans under § 422.101(d)(2) and (3).

To better reflect how finalized § 422.100(f)(4) applies to catastrophic and total catastrophic (combined MOOP) limits, increase clarity in the regulations, and make necessary corrections from the February 2020 proposed rule to codify the range CMS has applied in calculating and evaluating compliance with these MOOP limits, we are also finalizing changes in § 422.101(d)(2) and (3). We are consolidating proposed § 422.101(d)(2) to clearly require MA regional plans to: (1) establish a catastrophic enrollee MOOP for basic benefits that are furnished by in-network providers that is consistent with § 422.100(f)(4); and (2) have the same MOOP type (lower, intermediate, or mandatory) for the catastrophic (in-network MOOP) limit and total

catastrophic (combined in-network and out-of-network expenditures) limit under § 422.101(d)(3).

In addition, we are adding new paragraphs (d)(3)(ii)(A), (B), and (C) in § 422.101. New paragraphs (d)(3)(ii)(A), (B), and (C) specify the ranges to determine if a plan's total catastrophic (combined MOOP) amount is considered a mandatory, intermediate, or lower MOOP type for purposes of §§ 422.100 and 422.101. These correspond to the ranges in § 422.100(f)(4)(i)(A) through (C) but are specific to the total catastrophic (combined MOOP) limits. Including these ranges for total catastrophic (combined MOOP) limits improves the regulation overall by providing more specificity in our codification of longstanding policy. As finalized in new § 422.101(d)(3)(ii)(A), (B), and (C), the ranges that define the type of total catastrophic (combined MOOP) limit (mandatory, intermediate, and lower) are as follows:

- Mandatory MOOP limit: One dollar above the in-network intermediate MOOP limit and up to and including the total catastrophic mandatory MOOP limit.
- Intermediate MOOP limit: One dollar above the in-network lower MOOP limit and up to and including the total catastrophic intermediate MOOP limit.
- Lower MOOP limit: Between \$0.00 and up to and including the total catastrophic lower MOOP limit.

This addition adds clarity to the regulation text and the ranges now codified in § 422.101(d)(3)(ii)(A) and (B) are consistent with our current practice for setting the lower and upper ranges of the total catastrophic MOOP limits.

Finalizing regulation text with these ranges explicitly described reflects a necessary correction to the proposed rule. Specifically, the approach in § 422.101(d)(3)(iii)(A) through (C) of having total catastrophic (combined MOOP) limits set one dollar above the in-network lower and intermediate MOOP limit amounts (for the total catastrophic (combined) intermediate and mandatory MOOP limits, respectively) is consistent with longstanding practice and reflects our current policy for how MA plans must have the same type of in-network and total catastrophic

(combined MOOP) amount (mandatory, intermediate, or lower). In the illustrative MOOP limits from Table 5 (Illustrative Example of Combined MOOP Limits for LPPO And Catastrophic (MOOP) Limits for RPPO Plans Based on Most Recent Medicare FFS Data Projections) in the February 2020 proposed rule, the lower range of the illustrative combined intermediate and mandatory MOOP types did not correctly reflect our intention to continue our current policy. For example, based on the illustrative in-network and combined MOOP limits for contract year 2022 provided in Tables 4 and 5 in section VI.A. of the February 2020 proposed rule, an MA plan that established an in-network intermediate MOOP of \$3,451 would have to establish a combined intermediate MOOP between \$5,151 and \$8,400, even if a plan wanted to establish a combined MOOP amount of \$4,000. Requiring an MA plan with an in-network MOOP amount to establish a combined MOOP amount that is one dollar above the combined lower MOOP limit (as shown in Table 5 from the February 2020 proposed rule) unnecessarily raises the combined MOOP amount rather than tying the lower range of the amount to the type of in-network MOOP amount chosen. As a result, the contract year 2023 in-network and total catastrophic (combined MOOP) limits in Table 5 reflect this finalized policy (as well as other changes more completely discussed in this section to apply the proposed rounding rules in § 422.100(f)(4)(iii), clarify how the application of the 10 percent cap on increases to the MOOP limits applies, and changes to the proposed ESRD cost transition discussed in section II.A.4.c. of this FC.). No changes in the approach to calculating the lower range of the combined lower MOOP limit are needed as the MOOP limits were shown to correctly reflect current practice by beginning at zero dollars in Table 5 from the February 2020 proposed rule. In summary, CMS will continue our longstanding approach by codifying the ranges finalized in §§ 422.100(f)(4)(i) and 422.101(d)(3)(ii) to determine if an MA organization is compliant with the finalized requirement in § 422.101(d)(2)(ii) (proposed in paragraph (d)(2)(i)) that the MA plan has the same type of innetwork and total catastrophic (combined MOOP) limit (mandatory, intermediate, or lower).

We are finalizing at § 422.100(f)(4)(iii) the rounding rules CMS uses for the MOOP limits generally as proposed but we are also finalizing new text to clarify and correct how the rounding rules at § 422.100(f)(4)(iii) are applied in calculating the in-network intermediate MOOP limit and all types of the catastrophic MOOP limits. In order to avoid applying the rounding rules in paragraph (f)(4)(iii) twice to calculate the in-network intermediate MOOP limit and to ensure that the resulting intermediate MOOP limit most closely reflects a numeric midpoint between the final mandatory and lower MOOP limits, we are finalizing a modification to paragraphs (f)(4)(iv)(B) and (v)(B). First, CMS will identify the unrounded mandatory and lower MOOP limits and apply the 10 percent cap on increases to the mandatory and lower MOOP limits from the prior year (as discussed in section II.A.4.c. in this FC). Second, CMS will identify the numeric midpoint of those two figures. Third, CMS will apply the rounding rules in paragraph (f)(4)(iii) to that numeric midpoint. The resulting figure is the intermediate MOOP limit. This process of calculating the intermediate MOOP limit is illustrated in Table 3. Specifically, Table 3 shows the calculations to set the contract year 2023 in-network intermediate MOOP limit following the methodology finalized in this FC. By basing the intermediate MOOP limit on the non-rounded, capped amounts used to calculate the final mandatory and lower MOOP limits, we are still calculating the intermediate MOOP limit as the numeric midpoint between the two MOOP limits as proposed. We are not finalizing any reference to the rounding rules in § 422.101(d)(2) because this modification to the provisions in § 422.100(f)(4) will apply to the catastrophic MOOP limits for in-network basic benefits for regional MA plans calculated under $\S 422.101(d)(2)$ because of how $\S 422.101(d)(2)$ cross-references $\S 422.100(f)(4)$. In addition, we are finalizing § 422.101(d)(3)(ii) with clarifying language about when the rounding rules are applied in order to avoid applying the rounding rules twice in calculating the total catastrophic MOOP limits for regional MA plans for contract year 2023 and subsequent years. We are also finalizing clarifying language about applying the 10 percent cap on increases to the mandatory and lower MOOP limits from the prior year when calculating the total catastrophic

MOOP limits. Specifically, for contract year 2023 and subsequent years, we will calculate the total catastrophic (combined MOOP) limits for regional MA plans by multiplying the respective non-rounded in-network MOOP limits (after application of the 10 percent cap on increases to the mandatory and lower MOOP limits from the prior year in § 422.100(f)(4)(iv) and (v)) by 1.5 and then applying the rounding rules to that figure. The rounded number will be the final upper range amount for the catastrophic limit for MA regional plans for combined in-network and out-of-network expenditures for basic benefits.

We believe these modifications to § 422.100(f)(4)(iv)(B) and (v)(B), and to § 422.101(d)(3)(ii) will result in more precise in-network intermediate MOOP limits and total catastrophic (combined MOOP) limits for future years. CMS completed the calculations of the in-network intermediate and total catastrophic (combined MOOP) limits for contract year 2023 following this methodology as shown in Tables 3 and 4. The final contract year 2023 in-network intermediate MOOP limits and total catastrophic (combined MOOP) limits in Table 5 reflect these updates (as well as the other changes for calculating MOOP limits finalized in this FC). MA plans must comply with the resulting final MOOP limits included in Table 5 for contract year 2023.

We are also finalizing additional and revised text in § 422.101(d)(2) and (d)(3) to clarify the scope of the regional MA plan MOOP amounts and the specific services to which the different MOOP limits apply: the catastrophic limit calculated under paragraph (d)(2) applies to in-network basic benefits and the total catastrophic limit calculated under paragraph (d)(3) applies to in-network and out-of-network basic benefits. We are finalizing a new paragraph (d)(3)(iii) to clearly require an MA organization to establish the total catastrophic MOOP amount (mandatory, intermediate, or lower) within the dollar range specified in paragraphs (d)(3)(ii)(A) through (C) and the type of MOOP limit will be used for purposes of §§ 422.100(f)(6), (j)(1), 422.101(d), and 422.113(b)(2)(v).

In large part the proposal was to describe and codify the methodology used for MOOP limits under CMS's policies first developed in a 2011 rulemaking for adopting MOOP limits beginning in 2012. As described in the February 2020 proposed rule, the OACT performs the data projections used for setting MOOP limits. Taking the most recent Medicare FFS data and developing projections for the contract year for which we will be calculating the MOOP limits necessarily involves informed judgment and the making of actuarial assumptions. CMS and the OACT have been guided by generally accepted actuarial principles and practices in developing the projections used for calculating the MOOP limits. The proposal implicitly acknowledged this in its description of how the OACT analyzes the relevant data to develop the projections in the preamble of the February 2020 proposed rule. Specifically, the February 2020 proposed rule discussed how the OACT conducted necessary analyses and projections in the past and made clear that the OACT would be involved in applying the methodologies to calculate the MOOP limits we were proposing. CMS will continue to use generally accepted actuarial principles and practices in finalizing the projections of beneficiary out-of-pocket costs that form the basis of the methodology to calculate MOOP limits. As a result, we are also finalizing new § 422.100(f)(7) to ensure that this FC provides more detail regarding the actuarial nature of how Medicare costs are projected which we believe is better stated in the regulation text. These principles permit discretion and the exercise of actuarial judgment; as a result, different actuaries and analysts may come to different, equally appropriate, projections. Actuaries often consider different methodologies and assumptions to project the effect of uncertain events¹⁰. Generally, data from full calendar years would be used (and may be full data or samples based on full data), but specific trends and/or utilization patterns from more recent periods may be considered even if the Medicare FFS program and/or more recent utilization information from MA encounter data are from incomplete years. The projections of the percentiles that determine MOOP limits may be affected in limited situations by changes in legislation (such as, changes in Medicare benefits),

 $^{^{10}} http://www.actuarial standards board.org/prof counts/asop-no-1-and-professional-judgment/. \\$

payment policy changes, significant region-specific events (such as, natural disasters), or other emergency situations. As the OACT determines their projections, trend factors are applied (consistent with the most recent Medicare Trustees Report). For example, the OACT will apply trend factors that reflect the expected volatility and impact of COVID-19 on Medicare FFS utilization data from prior years in order to determine the Medicare FFS data projections for 2023 and subsequent years that CMS will use in calculating MOOP limits for those years. This approach is consistent with accepted actuarial standards of practice in that actuaries may use their professional judgment when selecting methods and assumptions, conducting an analysis, and reaching a conclusion. We reiterate that this is an example and that CMS and the OACT may exercise actuarial judgment in other matters as appropriate based on the regulatory standard being finalized at paragraph (f)(7)(i). CMS may explain the significant, professional actuarial judgments the OACT considered and solicit comment from stakeholders through the subregulatory process finalized in paragraph (f)(7)(iii) prior to final issuance of the MOOP limits and cost sharing standards for a future contract year. CMS may also describe how the OACT reached the projections used to calculate MOOP limits, if applicable and appropriate. For contract year 2023, the Medicare FFS data projections of the 95th and 85th percentiles included in row D of Table 2 reflect the OACT's actuarial judgements of expected costs in contract year 2023, including considerations of the impact from COVID-19. In summary, we are finalizing paragraph (f)(7)(i) to ensure transparency about the standards applied in developing the projections used in the methodologies for calculating the MOOP limits in §§ 422.100(f)(4) and (f)(5), and 422.101(d)(2) and (d)(3) will be applied using generally accepted actuarial principles and practices.

As discussed in more detail in section II.B of this FC, new § 422.100(f)(7) will also apply to how cost sharing standards in paragraph (f)(6) and (j) are calculated and evaluated using the methodologies adopted in this FC. Accordingly, we also discuss this new regulatory paragraph as it relates to cost sharing standards in section II.B. of this FC. Next, we address comments

received on the ESRD cost transition schedule, explain how CMS's calculations of MOOP limits are impacted by ESRD costs, and more specifically address how the MOOP limits will be set for 2023 and future years in section II.A.4.c. of this FC.

c. Multiyear Transition of ESRD Costs into the Methodology for MOOP Limits and Post-Transition Changes in the MOOP Limits (§ 422.100(f)(4)(iv) through (vi))

CMS proposed to conduct a multiyear transition of ESRD costs into the methodology for how we calculate MOOP limits. Section 1851(a)(3) of the Act, as amended by section 17006 of the 21st Century Cures Act, amended the Medicare statute to permit Medicare beneficiaries with diagnoses of ESRD to enroll in MA plans beyond the previous enrollment limitations, beginning in contract year 2021. Before these amendments were effective for contract year 2021, individuals diagnosed with ESRD could not enroll in a MA plan, subject to limited exceptions. In the proposed rule, we explained that the data CMS uses to calculate the MOOP limits should also incorporate the out-of-pocket expenditures of beneficiaries with diagnoses of ESRD, which we are referring to in this FC as "ESRD costs," to reflect this statutory change. We also proposed safeguards to protect against excessive changes in the MOOP limit during and after the ESRD cost transition. Since the February 2020 proposed rule, OACT studied the impact of expanded ESRD enrollment eligibility for the MA program on MA benefits using 2021 Medicare data and has estimated the impact to be \$-0.45 PMPM which is the weighted average for all MA plans.

Comment: A commenter noted that the February 2020 proposed rule did not include Table 11, to which CMS referred (85 FR 9076) to illustrate how the transition of ESRD costs into the MOOP limit calculations would work.

Response: The references to Table 11 in the February 2020 proposed rule preamble (85 FR 9076) were incorrect. We should have referenced Table 4, titled "Table 4 – Illustrative Example of In-Network MOOP Limits Based on Most Recent Medicare FFS Data Projections."

As indicated in the context of the February 2020 proposed rule and the table title, Table 4

illustrated the transition of the ESRD cost differential into the MOOP limit calculations using projections of Medicare FFS cost based on 2015 to 2019 Medicare FFS data (85 FR 9077).

Comment: Many commenters were generally concerned about the potential effects from enrollee subsidization of ESRD costs and believed passing the financial burden of ESRD care on to enrollees is not an appropriate solution. The commenters noted non-ESRD enrollee subsidization of ESRD costs may produce negative downstream effects on MA enrollment, plan options, premiums, supplemental benefits (including SSBCI), care coordination services, and access to lower MOOP and cost sharing limits. A commenter that opposed the transition of ESRD costs into MOOP limits acknowledged that some increase may be justified but stated that the incorporation of ESRD costs simply raises costs for all beneficiaries and was similarly concerned about non-ESRD enrollees subsidizing costs associated with enrollees with diagnoses of ESRD.

A commenter, in referencing a Wakely actuarial consulting firm study¹¹, suggested MA organizations may raise enrollee premiums by as much as \$18 per member per month, or reduce benefits by a similar magnitude, or limit plan options, to cover the increase in plan expenses due to covering enrollees with diagnoses of ESRD. Another commenter mentioned that MA organizations may redirect MA rebate dollars, normally used for benefit enhancements such as reduced cost sharing and mandatory supplemental benefits, to instead cover the additional ESRD costs. A commenter noted that while some cost subsidization across all MA enrollees is inherent to the design of the MA program, the commenter did not believe that increasing the cost burden for all MA enrollees is a sustainable solution for higher costs caused by an increased number of ESRD beneficiaries in the MA program. Another commenter urged CMS to give equal consideration to containing out-of-pocket costs for all Medicare beneficiaries.

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¹¹ Tim Courtney and Rachel Stewart, Wakely Consulting Group. "2021 Medicare Advantage Advance Notice," March 4, 2020 https://www.ahip.org/2021-medicare-advantage-advance-notice/

Response: We believe conducting a multiyear transition of ESRD costs into our methodology for setting MOOP limits is an important and necessary step to ensure plan designs are not discriminatory and protect beneficiaries from significant changes in out-of-pocket costs regardless of the MA plan they choose. As the MOOP limits will apply to enrollees with and without diagnoses of ESRD, the data CMS uses to calculate the MOOP limits should include out-of-pocket expenses from beneficiaries with and without diagnoses of ESRD similar to how costs for other high cost health conditions are included in the Medicare FFS data used to calculate MOOP limits.

We appreciate that some MA plans anticipate increased costs associated with covering the cost of care for individuals with diagnoses of ESRD. An analysis conducted by the OACT demonstrates that the ESRD open enrollment opportunities beginning in 2021 are expected to have a limited impact on both the financial outcomes of MA organizations and the corresponding benefits and premiums of the MA program. The primary reasons for the relatively small effect are that the increase in projected MA ESRD enrollment will represent a small fraction of membership in MA plans and that any financial effects will be diluted across existing plan membership. For the base data for this analysis, the OACT used the 2019 ESRD experience submitted by MA organizations as part of their 2021 bids. Increases in MA enrollment of beneficiaries with ESRD due to the expanded ESRD enrollment eligibility were estimated based on prior baselines that did not include this expansion. The expectations are that the projected movement of beneficiaries with ESRD into the MA program will result in slightly decreased MA margins. The Medical Loss Ratio (MLR) for ESRD enrollees is projected to be higher than the MLR for non-ESRD enrollees. The MLR is expressed as a percentage, generally representing the percentage of revenue used for patient care, rather than for such other items as administrative expenses or profit. In general terms, the MLR is inversely correlated with margins; higher MLRs are normally associated with lower margins. The impact of the MA margin change on MA benefits was estimated based on the assumption that MA organizations will recoup the losses

(gains) stemming from increased ESRD enrollment through a reduction (increase) in the margin represented in the MA bid. Using the revised bid margin assumption, we recalculated the key bid values, including the plan bid, MA rebate, and MA basic premium, if applicable. Combining these assumptions, the enrollment-weighted average estimated change in net MA benefits resulting from the ESRD enrollment expansion is –\$0.45 PMPM for contract year 2021.

As provided in section 1853(a)(1)(H) of the Act, CMS establishes separate rates of payment to MA organizations for ESRD beneficiaries enrolled in MA plans. See also §§ 422.254 and 422.304 through 422.308. The rates used for enrollees in dialysis or transplant status are based on statewide average Medicare FFS costs for ESRD beneficiaries in dialysis status. For enrollees with functioning graft status, the MA county benchmark rates are the payment rates. The rates for those in dialysis, transplant, and functioning graft status are also adjusted using a risk adjustment methodology that is specific to the health care costs for beneficiaries with ESRD in dialysis, transplant or functioning graft status. The proposal being finalized here was about how the MOOP limits should be calculated, including the data used and the percentiles of Medicare FFS data projections that should be used in those calculations.

We proposed to transition the out-of-pocket costs for beneficiaries who have diagnoses of ESRD into the methodology CMS uses to calculate MOOP limits over multiple years to avoid sudden and significant changes, which would be disruptive to enrollees. A sudden and significant shift in the MOOP limits – which would happen if the MOOP limits were increased by 100 percent of the ESRD cost difference in one year – is not consistent with protecting enrollees from disruptive year over year benefit or cost sharing changes. In this manner, we believe our approach gives equitable consideration to containing out-of-pocket costs for all current and potential MA enrollees.

CMS acknowledges and understands that some plans may adopt a mandatory MOOP type. However, we expect MA organizations will continue to offer favorable benefit designs that meet beneficiary needs, are competitive, and are attractive to beneficiaries. In addition, MA

organizations have multiple strategies to manage care and costs through provider contracting, care coordination, case management, plan benefit designs, and benefit flexibilities including SSBCI and MA uniformity flexibility. As such, CMS believes MA organizations have the opportunity to design affordable benefit packages that are tailored to beneficiary needs. CMS does not expect the potential negative downstream effects on MA enrollment, plan options, premiums, supplemental benefits (including SSBCI), care coordination services, and access to lower MOOP limits, referenced by the commenters, to come to fruition solely due to the provisions in this FC.

Comment: A few commenters were concerned that the ESRD cost transition and the resulting MOOP limits would promote adverse selection of certain MA plans by enrollees with diagnoses of ESRD. These commenters noted that the nature of the needed medical care to manage ESRD is ongoing, complex, and will consistently produce annual health care costs that significantly exceed the projected lower MOOP limit. Commenters believe these factors will result in beneficiaries with diagnoses of ESRD being disproportionately attracted to and enrolling in MA plans with lower MOOP limits. A commenter noted that this would place a heavier cost burden on MA plans that endeavor to keep costs low for beneficiaries than for plans who maintain higher MOOP limits.

Response: We understand the concern about potential adverse selection that may result when MA plans establish a lower MOOP type for beneficiaries that generally have higher health care costs, including beneficiaries with diagnoses of ESRD. While some MA organizations have experience in managing the health care services for beneficiaries with diagnoses of ESRD, under the prior enrollment policy, the proposals on MOOP limits and cost sharing standards, which we are finalizing with some modifications, provide incentives in the form of cost sharing flexibilities to MA organizations that adopt MOOP amounts below the mandatory level. Further, MA plans can utilize effective risk mitigation strategies, contracting arrangements, and care management policies in conjunction with the addition of the cost sharing flexibilities. For example, the

People-to-People Health Foundation reported MA SNP enrollees had lower mortality and lower rates of utilization across the care continuum in comparison to Medicare FFS beneficiaries and stated that SNPs may be an effective alternative care financing and delivery model for patients with diagnoses of ESRD¹². Unlike past years, MA plans adopting a mandatory MOOP type in the future will have limited cost sharing flexibility for most service category standards compared to other MOOP limits (for example, the cost sharing limit will be reduced from 50 percent coinsurance in 2022 to 30 percent by contract year 2026 for most professional standards). CMS establishes separate rates of payment to MA organizations for ESRD beneficiaries enrolled in MA plans; the rates used for enrollees in dialysis or transplant status are based on statewide average FFS Medicare costs for ESRD beneficiaries in dialysis status and are subject to risk adjustment. Therefore, as the MA ESRD rates are based on FFS costs, higher costs of covering medically necessary benefits for beneficiaries with ESRD are factored into setting the payments to MA plans for enrollees with ESRD. As a result, we do not believe that the concern about adverse selection is as significant as it might otherwise be.

Further, we did not propose or discuss increasing MOOP limits or plan premiums for only beneficiaries with diagnoses of ESRD. Consistent with sections 1852(d) and 1854(c) of the Act, MA regulations at §§ 422.100(d), 422.254(b), and 422.262(c) require benefits, cost sharing, and premiums for enrollees to be uniform. Our interpretation of uniformity may permit an MA plan to reduce, not increase, cost sharing for similarly situated enrollees in order to address specific health needs of the enrollees (such as, lower cost sharing for enrollees with diabetes to see an endocrinologist). Section 422.100(d), which was finalized in section V.C. of the January 2021 final rule to codify our interpretation of uniformity, does not authorize lower cost sharing or increased benefits for healthier enrollees. The requirement for uniform benefits is also subject to the waiver of uniformity that may be provided for an MA plan to target specific Special

¹² Powers, et al. "The Beneficial Effects Of Medicare Advantage Special Needs Plans For Patients With End-Stage Renal Disease" September 2020

Supplemental Benefits for the Chronically III (SSBCI) under § 422.102(f) and how optional supplemental benefits are only provided for enrollees who elect to pay the extra premium for that coverage under § 422.101(c)(2). The ability to offer supplemental benefits that have a connection with a specific health condition is permitted only for reductions in cost sharing and additional benefits, not for decreasing benefits, and requires the supplemental benefit to be available to all similarly situated enrollees. We did not propose to permit an MA plan to apply MOOP amounts (or other cost sharing standards) in a non-uniform manner and are not finalizing any authority for that. CMS's proposal discussed calculating MOOP limits that are applied uniformly to all MA plan enrollees to cap the MOOP costs for enrollees, protect beneficiaries, and prevent discrimination against enrollees with significant health care needs. Our proposal necessarily encompassed projected future increases to the MOOP limits but those increases are also to be uniformly applied. In addition, plan premiums are applied uniformly across plan enrollees (except for EGWPs that use a waiver of the requirement for uniform premiums) and cannot be targeted to specific beneficiaries or those with certain health conditions. Because of these uniformity considerations, we do not believe that the methodology for calculating the MOOP limits or the incorporation of the ESRD cost differential into the data that is used to calculate the MOOP limits will result in adverse selection or discrimination against beneficiaries with diagnoses of ESRD.

<u>Comment:</u> A commenter believed the proposal to transition the out-of-pocket costs for beneficiaries with diagnoses of ESRD into the data used to set MOOP limits would result in an increased MOOP limit only for enrollees with diagnoses of ESRD and stated that an \$850 increase in the mandatory MOOP limit is insufficient for MA organizations to cover the ESRD-related costs for this population.

Response: We reiterate that as proposed and finalized, the MOOP limits may not be applied so that enrollees with diagnoses of ESRD have a higher MOOP amount than enrollees without these health conditions. A more complete discussion of the uniformity aspects of CMS's

MOOP limits proposal is available in section II.A.4.a. of this FC and in a previous response to comment in this section. Although the commenter stated that initial increases to MOOP limits proposed for contract year 2022 (in essence, the first year we proposed to apply the changes) were insufficient to cover the increased costs that are projected for enrollees with diagnoses of ESRD, the MOOP limits are projected to further increase in future years based on our proposal to incorporate more of the ESRD cost differential.

As discussed in greater detail subsequently in this section, CMS will limit the potential increase in MOOP limits to a cap of 10 percent compared to the MOOP limits set for the prior year (beginning with contract year 2023). As illustrated in Tables 2 and 3 and reflected in the final MOOP limits for contract year 2023, the in-network contract year 2023 mandatory MOOP limit has been capped at a 10 percent increase based on the contract year 2022 mandatory MOOP limit. This means the mandatory MOOP limit for contract year 2023 does not fully reflect the 95th percentile of Medicare FFS data projections as doing so would result in an increase greater than 10 percent compared to the contract year 2022 mandatory MOOP limit. Applying this cap on the amount of potential increase each year to the MOOP limits is an important beneficiary protection and consistent with how we have previously balanced the goal of limiting enrollee costs (to avoid plan designs that discourage enrollment by sicker beneficiaries) and ensuring continued access to affordable and sustainable benefit packages when setting MOOP limits.

Comment: A few commenters who were opposed to the ESRD cost transition generally encouraged CMS to explore alternative solutions to account for the approximately \$6,300 difference between the existing mandatory MOOP limit (\$6,700) and the average annual out-of-pocket costs for beneficiaries with ESRD in Medicare FFS (\$13,042¹³ based on data from 2015-2017) rather than raising the MOOP limit (as projected from incorporating the ESRD cost differential into the out-of-pocket costs used to establish the MOOP and cost sharing limits).

¹³Health Management Associates. "End-Stage Renal Disease and Medicare Advantage." February 12, 2019. The most recent report is available online at: https://www.healthmanagement.com/wp-content/uploads/Health-Management-Associates-ESRD-and-Medicare-Advantage-White-Paper.pdf

Some of these commenters referenced data analyses completed by MedPAC¹⁴ and the Kaiser Family Foundation (KFF)¹⁵ that found that the average cost of covering Medicare beneficiaries with ESRD is significantly more than the healthcare costs of an average MA beneficiary. Another commenter also referred to the research finding that applying the mandatory MOOP limit to ESRD beneficiary spending results in increased MA costs by an estimated 8 to 9 percent on average when compared to Medicare FFS spending¹⁶. A commenter described this data from the perspective that every ESRD enrollee effectively represents an outlier compared to the current average costs of care for other beneficiaries. Another commenter was concerned about the possibility of MA plans discriminating against and discouraging beneficiaries with diagnoses of ESRD from enrolling in the MA program.

In a related note, a few commenters encouraged CMS to consider how coverage costs for ESRD patients can be significantly above or below the overall state average in certain locales, such as metropolitan areas in California, Florida, Ohio, and Texas. A commenter referenced the Avalere Health analysis of 2018 Medicare FFS claims data that found 10 of the top 15 metropolitan statistical areas with the most ESRD patients had costs that exceeded the MA payment rate. Given the research, a few commenters suggested that most, if not all, enrollees with diagnoses of ESRD will surpass the highest allowable, mandatory MOOP limit despite projected increases from the proposed ESRD cost transition.

Response: We appreciate the commenters' feedback and requests to consider alternatives to raising the MOOP limits to protect beneficiaries from increases in their out-of-pocket costs.

¹⁴ MedPAC. June 2019. Section 2: Medicare Beneficiary Demographics. June 2019 Data Book: Health Care Spending and the Medicare Program. The most recent version of MedPAC's annual data book may be retrieved from: https://www.medpac.gov/document-type/data-book

¹⁵ KFF, "Medicare Beneficiaries With End-Stage-Renal Disease (ESRD)," 2019

https://www.kff.org/medicare/state-indicator/enrollees-with-

esrd/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D

¹⁶ Health Management Associates. "End-Stage Renal Disease and Medicare Advantage." February 12, 2019. The most recent report is available online at: https://www.healthmanagement.com/wp-content/uploads/Health-Management-Associates-ESRD-and-Medicare-Advantage-White-Paper.pdf.

¹⁷ Kazan et al, Avalere Health, "Medicare Advantage Plans May Be Paid Below Actual ESRD Patients' Costs in Large Metropolitan Areas in 2021" December 2019 https://avalere.com/insights/medicare-advantage-plans-may-be-paid-below-actual-esrd-patients-costs-in-large-metropolitan-areas-in-2021

Under the current regulation, MA MOOP limits have been based on stable percentiles of Medicare FFS spending. This approach supports our goal of ensuring that all eligible beneficiaries have access to affordable and sustainable benefit packages. Our approach to incorporate costs of beneficiaries with diagnoses of ESRD in setting MOOP limits is consistent with the approach CMS has historically used of spreading the burden of medical costs across all potential MA enrollees uniformly through the continued use of the 95th and 85th percentiles of out-of-pocket spending for the population that is eligible to enroll in an MA plan. Historically, CMS has tried to balance between limiting beneficiaries' maximum out-of-pocket costs and potential changes in premium, benefits, and cost sharing, with the goal of ensuring beneficiary access to affordable and sustainable benefit packages. This practice avoids discriminating against beneficiaries with diagnoses of ESRD – or any group of beneficiaries with a particular high cost condition or health status – that would result if there were higher premiums, cost sharing, or MOOP amounts applicable only to those individuals with a certain chronic condition. Excluding the out-of-pocket costs for beneficiaries with diagnoses of ESRD from the data used to calculate the MOOP limits might serve to keep the out-of-pocket expenses borne by MA enrollees lower, but would not be consistent with ensuring access to affordable and sustainable benefit packages for all eligible beneficiaries because it would result in a significant increase in the costs that exceed the MOOP limit and therefore are borne by the MA organization. Increasing the coverage costs for MA organizations could lead to other increases in premiums or decreases in benefits. Further, calculating the MOOP limits at a level that is significantly less than the 85th and 95th percentiles of beneficiary out-of-pocket spending is not as consistent with the underlying purpose for adopting the MOOP: ensuring that beneficiaries that are most likely to be discriminated against – those beneficiaries who have much higher health care needs – are not discouraged from enrolling in an MA plan.

We acknowledge that as beneficiaries with diagnoses of ESRD enroll in greater numbers into the MA program, MA organizations will more often than before have to cover the costs

associated with that chronic condition when these enrollees meet the plan's MOOP amount and incur more costs past the MOOP than enrollees without diagnoses of ESRD are projected to do, on average. CMS uses historical FFS reimbursement and enrollment data for beneficiaries with diagnoses of ESRD to develop the rates used to pay MA organizations for these enrollees, which are generally higher than the rates paid to MA organizations for enrollees without diagnoses of ESRD. CMS believes without incorporating ESRD costs into the MOOP limits, MA plans may have a greater likelihood of increasing premiums for all enrollees or reducing benefits to address the expected increased costs associated with additional enrollment of beneficiaries with diagnoses of ESRD. Guarding against those outcomes is consistent with the standard CMS uses to calculate the MOOP limit under current §§ 422.100(f) and 422.101(d) and part of our rationale for incorporating the ESRD cost differential. We believe that it is important for the MOOP limits to be calculated using data regarding the out-of-pocket expenses of beneficiaries with and without diagnoses of ESRD because the MOOP limits will apply to enrollees with and without diagnoses of ESRD.

MA organizations serve different geographic areas and ESRD enrollment and spending may vary across metropolitan areas and states. It would be overly complex to set MOOP limits by geographic area. For example, some complicating factors include: medical economics in different geographic areas; how to reasonably define geographic areas; varying negotiating leverage of MA organizations and resources; and potential resulting complexities for beneficiaries in evaluating plan options. Also, it would be difficult to incorporate the remainder of the ESRD cost differential at a rate that was consistent with the enrollment rate of beneficiaries with diagnoses of ESRD in specific geographic areas. Finally, setting geographically specific MOOP limits was not proposed.

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¹⁸ The Calendar Year 2021 and 2022 Rate Announcements may be accessed at https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents.

Comment: Some commenters requested CMS modify the ESRD cost transition schedule to match projected enrollment changes or actual enrollment of beneficiaries with diagnoses of ESRD. For example, a commenter requested CMS delay finalizing the complete ESRD cost transition schedule until the actual year-1 penetration rate of beneficiaries with diagnoses of ESRD in the MA program can be assessed. In addition, this commenter requested (if the actual penetration rates were not used) that CMS match the ESRD cost transition rate to OACT's projected rate of transition of beneficiaries with diagnoses of ESRD into the MA program.

Response: CMS endeavors to calculate and issue these MOOP limit and cost sharing standards sufficiently in advance of the bid deadlines (typically by the first Monday in April, as discussed in section II.A.4.b. of this FC, when capitation rates and payment policies are announced for the upcoming year) to provide MA organizations with sufficient time to develop their bids. In addition, we did not propose to set the schedule for transitioning ESRD costs into MOOP limits based upon OACT's projection of ESRD enrollment because actual ESRD enrollment per plan may vary and OACT's analysis reflects expectations for the MA program as a whole. Using the penetration and enrollment rates from the prior year to transition the ESRD cost differential would not truly address the issue raised by the commenter (that is, the amount of the ESRD cost differential used in calculating the MOOP limit for a year is not the same as the MA enrollment rate of beneficiaries with diagnoses of ESRD for that year). The time lag between: (1) the enrollment information we have available at the time we calculate the MOOP limits; and (2) the contract year for which the MOOP limits are applied would mean that there would always be a disconnect between the enrollment numbers and the MOOP limit. In addition, as previously summarized in this section, it would be overly complex to set MOOP limits by geographic area and incorporate the remainder of the ESRD cost differential at a rate that was consistent with the enrollment rate of beneficiaries with diagnoses of ESRD in specific geographic areas.

While we appreciate the commenter's suggestion to align the ESRD cost transition schedule with the OACT's projected rate of ESRD enrollment, we believe this would add another layer of complexity and further delay the transition process. As discussed in the February 2020 proposed rule, the OACT expected ESRD enrollment in MA plans to increase by 83,000 beneficiaries as a result of the 21st Century Cures Act provision. The OACT assumed the increase would be phased in over 6 years, with half of those beneficiaries (41,500) enrolling during 2021; the remaining 41,500 additional beneficiaries were expected to enroll in MA plans during the years 2022 to 2026 under the assumption that the number of additional enrollees who have diagnoses of ESRD will continue to increase during that time frame though at a decreasing rate in later years. Based on actual 2021 enrollment data, the OACT continues to project that 83,000 beneficiaries with diagnoses of ESRD will enroll in the MA program over 6 years. If CMS were to match the transition of incorporating ESRD costs to that of OACT's enrollment projections, we would be forced to delay the full transition of ESRD costs until 2026. After publication of the February 2020 proposed rule, CMS announced that it would take the Medicare FFS costs of beneficiaries with diagnoses ESRD into account in developing MOOP and cost sharing limits for 2021.¹⁹ The contract year 2021 MOOP limits (which encompassed 40 percent of the ESRD cost differential) were maintained for contract year 2022 while enrollment of beneficiaries with diagnoses of ESRD is projected to increase.²⁰ As a result, CMS believes any further delays to the ESRD cost transition would not be beneficial as only 40 percent of the ESRD cost differential has been incorporated up to contract year 2022, the year the OACT projected total enrollment of beneficiaries with diagnoses of ESRD into the MA program to exceed 50 percent. In addition, when developing our proposed ESRD cost transition schedule, we considered how OACT's aggregate projections may not reflect the experiences in all

¹⁹ See the HPMS memorandum titled "Final Contract Year 2021 Part C Benefits Review and Evaluation," issued April 8, 2020 for information on MOOP limits for contract year 2021.

²⁰ See the HPMS memorandum titled "Final Contract Year 2022 Part C Benefits Review and Evaluation," issued May 20, 2021 for information on MOOP limits for contract year 2022.

geographic locations, which could have different rates of transition and changes in expenditures for providing care to beneficiaries with diagnoses of ESRD.

Comment: As summarized in this section, CMS received many comments relevant to the solicitation in the February 2020 proposed rule on whether the ESRD cost transition schedule proposed at § 422.100(f)(4)(vii) aligns with the goals of providing predictable and transparent MOOP limits and cost sharing standards, minimizing significant new costs for MA plans or enrollees, and providing flexibility if the ESRD cost differential transition needs to be adjusted. Most commenters supported a multi-year transition of ESRD costs into the MOOP limits, but recommended changes to accelerate or simplify the transition. Some commenters who were supportive of the proposed transition schedule, or who did not solely tie their concerns to the proposed schedule of transitioning ESRD costs into the methodology for setting MOOP limits at paragraph (f)(4)(vii), shared concerns addressed in previous comment summaries in this section (namely, negative effects from costs associated with enrollees with diagnoses of ESRD being subsidized by other enrollees without these diagnoses; adverse selection of MA plans by enrollees with diagnoses of ESRD; and the possibility of MA plans discriminating against and discouraging beneficiaries with diagnoses of ESRD from enrolling in the MA program). A commenter who supported the transition noted that the projected MOOP limit increases over time would allow flexibility for MA organizations to adjust to the costs of covering enrollees with diagnoses of ESRD and that the gradual implementation of higher MOOP limits will minimize impacts (such as, additional cost sharing or increased premiums) on enrollees. Another commenter supported the ESRD cost transition schedule as proposed.

Several commenters recommended accelerating or simplifying the ESRD cost transition because: (1) a lengthy, complex or confusing transition would be difficult for MA organizations to plan and execute; (2) a longer transition would not support MA plans managing the higher ESRD costs quickly enough; and (3) delaying the transition may require premium increases to fully cover or subsidize ESRD member costs. A commenter requested CMS complete the

transition over 3 years, instead of 4 years, by incorporating 25 percent of the ESRD cost differential each year as follows: 50 percent in 2021, 75 percent in 2022, and 100 percent of all ESRD costs incorporated in 2023. In addition, a few commenters were concerned that the OACT's projections of beneficiaries with diagnoses of ESRD that will enroll in an MA plan during the next several years is understated. A commenter explained that even if only a small number of beneficiaries with diagnoses of ESRD migrate from Medicare FFS to the MA program, MA organizations will face significantly increased medical care costs. This commenter also stated that CMS's phase-in proposal for the ESRD cost differential was understating the speed at which beneficiaries with ESRD will transition to MA plans. A commenter that wanted to accelerate the transition was also concerned that as beneficiaries with diagnoses of ESRD migrate to MA and fewer remain in Medicare FFS, CMS's methodology of calculating MOOP limits using both non-ESRD and ESRD costs would result in MOOP limits being set too low and would fail to achieve an actuarially equivalent level of cost sharing. Specifically, this commenter noted that the substantial financial benefits of the MOOP limit for ESRD members would result in the ultimate blending (of out-of-pocket costs for all beneficiaries) being insufficient if the penetration rate of ESRD members in MA plans ends up exceeding that of non-ESRD members.

Response: In response to the comments we received (summarized in this section) and given the timing of this FC, we are finalizing some changes to the schedule for incorporating the ESRD cost differential into the Medicare FFS cost data used in the methodology for calculating the MOOP limits each year (and also used in the methodology for calculating inpatient hospital acute and psychiatric cost sharing limits, as discussed in section II.B. of this FC). The transition schedule was proposed as follows: 60 percent in 2022; 80 percent in 2023 or next year; and 100 percent in 2024 or the final year of transition. This was proposed in the context of the 2021 MOOP limits being based on Medicare FFS data projections that incorporated 40 percent of the ESRD cost differential. In addition, we proposed guardrails to pause the incorporation of the

increase or decrease in the limits from the prior year, if the dollar figure at the 85th or 95th percentile of projected Medicare FFS costs increased or decreased by a difference of more than two percentiles above or below the 85th and 95th percentile from the prior year. The combination of the transition and guardrails was designed to strike a balance of providing plan benefit design stability while also protecting beneficiaries from rapid premium or cost sharing changes. We respond to general concerns regarding potential beneficiary discrimination tied to the MOOP limit methodology in section II.A.4. of this FC and to concerns related to enrollee subsidization of ESRD costs and potential adverse selection in previous responses in this section.

We appreciate the recommendations about the timing to incorporate ESRD costs into the data used to calculate MOOP limits (and inpatient hospital acute and psychiatric cost sharing limits). In this FC, we are finalizing the use of a transition schedule combined with guardrails on overall increases with some modifications compared to the proposal. We are finalizing the definition and use of the ESRD cost differential as a specific way to measure ESRD costs and factor them into the data (and the methodology CMS uses to calculate annual MOOP limits) with moderate modifications based on commenter feedback. We are finalizing a modification to the ESRD cost differential definition at § 422.100(f)(4)(vi) (proposed in paragraph (f)(4)(vii)) to clarify that this value is the difference between, first, for the mandatory MOOP limit, \$7,175 and for the lower MOOP limit, \$3,360 and second, for the mandatory MOOP limit, the 95th percentile and, for the lower MOOP limit, the 85th percentile of the Medicare FFS data projections for each year between 2023 and 2024. The proposed definition mistakenly referred only to using costs incurred by beneficiaries with ESRD and did not fully clarify the specific comparisons being made for the mandatory and lower MOOP types. We note using the "Medicare FFS data projections" term as defined in paragraph (f)(4)(i) ensures that the ESRD cost differential compares the 95th and 85th percentiles of the projected out-of-pocket costs for Medicare FFS beneficiaries with and without diagnoses of ESRD for the upcoming year to the \$7,175 and \$3,360 dollar amounts in order to calculate the ESRD cost differential for that year

(as discussed in the February 2020 proposed rule). We believe that clarification on these points improves the regulation text. We also added language to paragraph (f)(4)(vi) to clarify that the ESRD cost differential is used in the ESRD cost transition finalized throughout paragraph (f)(4). Because the Medicare FFS data projections will be updated each year with more recent data, references to different projections in this FC include the contract year that the projections are for and the years of data that those projections are based on. For example, contract year 2023 Medicare FFS data projections (based on Medicare FFS data from 2017 to 2021) reflect the amounts CMS used to calculate the MOOP and cost sharing limits for contract year 2023.

As discussed in section V.H.1. of this FC, CMS considered several alternatives to implementing the proposed ESRD cost transition schedule into the methodology CMS uses to calculate MOOP limits based on public comments, the timing of this FC, potential for enrollee disruption, and impacts of further delays in integrating ESRD costs. After consideration of those alternatives, we believe finalizing a modified transition schedule would be beneficial and address the concerns and interests raised by the comments. The delay in finalizing this provision resulted in no increased ESRD cost adjustment for contract year 2022 MOOP limits (rather, the ESRD cost differential remained the same as 2021) while ESRD enrollment in MA is projected to increase in 2022. Specifically, CMS maintained the contract year 2021 MOOP limits for contract year 2022. Therefore, we are not finalizing a provision to address the incorporation of the ESRD cost differential for contract year 2022 (proposed at paragraph (f)(4)(vii)(A)) and are organizing the regulation text as necessary.

As a result, we are finalizing at § 422.100(f)(4)(vi)(A) and (B) that the ESRD cost differential will be factored into the Medicare FFS data projections used to calculate the MOOP limits as follows: for 2023, 70 percent and for 2024, 100 percent.

In finalizing use of 70 percent of the ESRD cost differential for 2023, we aim to strike a balance among curbing potential disruptive changes in MOOP limits from contract year 2022 to contract year 2023, avoiding the concerns with a lengthy transition identified by commenters,

and ensuring MA organizations can continue offering all plan enrollees, regardless of their ESRD status, quality care and service while keeping premiums and cost sharing at non-discriminatory levels. As finalized, § 422.100(f)(4)(iv) through (vi) reflects the updated timing for the finalized transition and includes some minor clarifications and edits to use consistent terminology. We expect these changes will help ensure that MA plans are able to both expand their membership to beneficiaries with diagnoses of ESRD and continue offering all enrollees, regardless of their ESRD status, high-quality health care and service while keeping premiums and out-of-pocket costs at reasonable levels for all enrollees.

The modified schedule we are finalizing to transition ESRD costs was used to update the MOOP limits from the illustrative figures provided in Tables 4 and 5 (Table 4, "Illustrative Example of In-Network MOOP Limits Based on Most Recent Medicare FFS Data Projections" and Table 5, "Illustrative Example of Combined MOOP Limits for LPPO and Catastrophic (MOOP) Limits for RPPO Plans Based on Most Recent Medicare FFS Data Projections") in the February 2020 proposed rule. In this FC, Table 5 contains the final MOOP limits for contract year 2023 and Table 9 contains illustrative MOOP limits for contract year 2024 for comparison purposes to Tables 4 and 5 from the February 2020 proposed rule. The calculations to reach the MOOP limits in Tables 5 and 9 are provided in Tables 2-4 and Tables 6-8. In addition, Tables 4, 5, 8, and 9 include a correction in the calculation of the lower ranges to the total catastrophic (combined MOOP) limits per § 422.100(d)(3)(iii), as discussed in section II.A.4.b. of this FC. CMS took public comments on the MOOP limit proposal from the February 2020 proposed rule into consideration regarding the use of a subregulatory notice and comment process before finalizing the MOOP and cost sharing limits each year and as discussed in sections II.A.4.b. and II.B.5. of this FC, we are adopting that process for the future. However, as this FC is not being published early enough to provide time for CMS to solicit comment and release subregulatory guidance before the contract year 2023 bid deadline, the MOOP limits contained in Table 5 are final. These limits were calculated applying the rules finalized in this FC. CMS intends to

update the illustrative contract year 2024 MOOP limits using contract year 2024 Medicare FFS data projections (based on Medicare FFS data from 2018 to 2022) when available and have a separate public comment period (based on § 422.100(f)(7)(iii)) before releasing the final contract year 2024 MOOP limits.

Using the 95th percentile of contract year 2023 Medicare FFS data projections (based on Medicare FFS data from 2017 – 2021), the projected percent increase to the mandatory MOOP limit for contract year 2023 would be greater than 10 percent in comparison to the mandatory MOOP limit set for contract year 2022. Table 2 compares the unrounded contract year 2023 innetwork mandatory MOOP limit before application of the 10 percent cap (\$8,530.20) to the mandatory MOOP limit set for contract year 2022 (\$7,550.00); this increase equates to approximately 13 percent (after accounting for the rounding rules which would raise the MOOP limit amount to \$8,550.00). As a result, Tables 2 through 5 illustrate application of the 10 percent guardrail for the mandatory MOOP limit in contract year 2023 to limit the increase to 9.9 percent after application of the rounding rules. Conversely, the percent increase of 5.8 percent to the lower MOOP limit for contract year 2023 is less than 10 percent in comparison to the voluntary MOOP limit set for contract year 2022. Similarly, comparing the highest allowable in-network mandatory and lower MOOP limits for contract year 2023 to the corresponding illustrative innetwork MOOP limits for contract year 2024 is less than 10 percent. For example, the final contract year 2023 in-network mandatory MOOP limit (\$8,300.00) compared to the illustrative unrounded contract year 2024 in-network mandatory MOOP limit (\$9,111.00) reflects an approximate 9.8 percent increase (and an approximate 3.3 percent increase for the illustrative lower MOOP limits). As a result, Tables 2 through 9 illustrate application of the 10 percent guardrails finalized in paragraphs (f)(4)(iv)(A) and (C) and (f)(4)(v)(A) when the increase threshold is met. These guardrails are also discussed more completely in a subsequent response to comment in this section.

Under § 422.100(f)(4)(vi), the ESRD cost differential for contract year 2023 is the difference between, first, for the mandatory MOOP limit, \$7,175 and for the lower MOOP limit, \$3,360 and second, for the mandatory MOOP limit, the 95th percentile (\$9,111.00) and for the lower MOOP limit, the 85th percentile (\$3,772.00) of the contract year 2023 Medicare FFS data projections (based on Medicare FFS data from 2017 to 2021). As shown in Tables 2 through 5, modifying the ESRD cost transition from the proposed 80 percent to 70 percent of the ESRD cost differential in contract year 2023 and completing the calculations using projections of Medicare FFS data from 2017 - 2021 (compared to the 2015 - 2019 Medicare FFS data available at the time of the February 2020 proposed rule), produced a moderate increase from the illustrative amounts contained in the February 2020 proposed rule. For example, the highest allowable (and illustrative) in-network mandatory MOOP limit was listed as \$7,950 for contract year 2023 in the February 2020 proposed rule. In comparison, as shown in Table 5, the final contract year 2023 highest allowable in-network mandatory MOOP limit is \$8,300 (an increase of \$350).

TABLE 2: CMS CALCULATIONS OF FINAL CONTRACT YEAR 2023 IN-NETWORK MANDATORY AND LOWER MOOP LIMITS USING PROJECTIONS OF 2017 – 2021 MEDICARE FFS DATA

Row		Mandatory MOOP	Lower MOOP
Reference	Description	Limit	Limit
A	Contract year 2022 MOOP limit	\$7,550.00	\$3,450.00
В	Maximum contract year 2023 MOOP limit per § 422.100(f)(4)(iv) (110% of row A)	\$8,305.00	\$3,795.00
С	Medicare FFS percentile in § 422.100(f)(4)	95 th	85 th
D	Unrounded contract year 2023 Medicare FFS data projections for the applicable percentile in row C ¹	\$9,111.00	\$3,772.00
Е	Baseline MOOP amount in § 422.100(f)(4)(iv)	\$7,175.00	\$3,360.00
F	Contract year 2023 ESRD Cost Differential per § 422.100(f)(4)(vi) (difference between row D and row E)	\$1,936.00	\$412.00
G	70% of the contract year 2023 ESRD Cost Differential per § 422.100(f)(4)(vi)(A) (row F multiplied by 0.7)	\$1,355.20	\$288.40
Н	Unrounded contract year 2023 MOOP limit prior to applying 10% cap on increases per § 422.100(f)(4)(iv) and (vi)(A) (row E plus row G)	\$8,530.20	\$3,648.40
I	Unrounded contract year 2023 MOOP limit with 10% cap on increases applied (the lesser value comparing row B and row H)	\$8,305.00	\$3,648.40
J	Rounded contract year 2023 MOOP limit per § 422.100(f)(4)(iii) and (iv) (row I rounded)	\$8,300.00	\$3,650.00
K	Lowest dollar range of the contract year 2023 MOOP limit per § 422.100(f)(4)(i)	\$6,001.002	\$0.003

Row		Mandatory MOOP	Lower MOOP
Reference	Description	Limit	Limit
L	Final contract year 2023 MOOP limit dollar ranges per § 422.100(f)(4)(i)	\$6,001.00 to	\$0.00 to
	through (iv) and (vi)	\$8,300.00	\$3,650.00

The OACT employed generally accepted actuarial principles and practices in calculating these projected amounts (as finalized in § 422.100(f)(7)).

The in-network mandatory MOOP limit dollar range begins at the value of the in-network intermediate MOOP limit from row D in Table 3 plus \$1.00 per § 422.100(f)(4)(i)(A).

The in-network lower MOOP limit dollar range begins at \$0.00 per § 422.100(f)(4)(i)(C).

TABLE 3: CMS CALCULATIONS OF FINAL CONTRACT YEAR 2023 IN-NETWORK INTERMEDIATE MOOP LIMIT PROJECTIONS OF 2017 – 2021 MEDICARE FFS DATA

Row		Intermediate MOOP
Reference	Description	Limit
A	Unrounded contract year 2023 mandatory MOOP limit with 10% cap on increases applied	\$8,305.00
	(row I, mandatory MOOP limit column in Table 2)	
В	Unrounded contract year 2023 lower MOOP limit with 10% cap on increases applied (row I,	\$3,648.40
	lower MOOP limit column in Table 2)	
С	Unrounded contract year 2023 intermediate MOOP limit per § 422.100(f)(4)(iv) (numeric	\$5,976.70
	midpoint between row A and row B)	
D	Rounded contract year 2023 intermediate MOOP limit (row C rounded per §	\$6,000.00
	422.100(f)(4)(iii))	
Е	Lowest dollar range of the contract year 2023 MOOP limit per § 422.100(f)(4)(i)(B)	\$3,651.00*
F	Final contract year 2023 intermediate MOOP limit dollar range per § 422.100(f)(4)(i)	\$3,651.00 to
	through (iv) and (vi)	\$6,000.00

^{*}The in-network intermediate MOOP limit dollar range begins at the value of the in-network lower MOOP limit from row J in Table 2 plus \$1.00 per § 422.100(f)(4)(i)(B).

TABLE 4: CMS CALCULATIONS OF FINAL CONTRACT YEAR 2023 COMBINED MOOP LIMITS FOR LPPO AND TOTAL CATASTROPHIC MOOP LIMITS FOR RPPO PLANS USING PROJECTIONS OF 2017 – 2021 MEDICARE FFS DATA

Row		Mandatory MOOP	Intermediate MOOP	Lower MOOP
Reference	Description	Limit	Limit	Limit
A	Corresponding unrounded in-network MOOP type with 10% cap on increases applied (values from row I in Table 2 and row C in Table 3)	\$8,305.00	\$5,976.70	\$3,648.40
В	Unrounded contract year 2023 combined and total catastrophic MOOP limit per § 422.101(d)(3)(ii) (row A multiplied by 1.5)	\$12,457.50	\$8,965.05	\$5,472.60
С	Rounded contract year 2023 combined and total catastrophic MOOP limit (row B rounded per § 422.100(f)(4)(iii))	\$12,450.00	\$8,950.00	\$5,450.00
D	Lowest dollar range of the contract year 2023 MOOP limit per § 422.101(d)(3)(ii)	\$6,001.001	\$3,651.002	\$0.003
Е	Final contract year 2023 combined and total catastrophic MOOP limit dollar ranges per § 422.101(d)(3)(ii)	\$6,001.00 to \$12,450.00	\$3,651.00 to \$8,950.00	\$0.00 to \$5,450.00

¹The combined and total catastrophic mandatory MOOP limit dollar range begins at the value of the in-network intermediate MOOP limit from row D in Table 3 plus \$1.00 per § 422.101(d)(3)(ii)(A).

TABLE 5: FINAL CONTRACT YEAR 2023 MOOP LIMITS BY PLAN TYPE

²The combined and total catastrophic intermediate MOOP limit dollar range begins at the value of the in-network lower MOOP limit from row J in Table 2 plus \$1.00 per § 422.101(d)(3)(ii)(B).

³The combined and total catastrophic lower MOOP limit dollar range begins at \$0.00 per § 422.101(d)(3)(ii)(C).

Plan Type	Lower MOOP Limit	Intermediate MOOP Limit	Mandatory MOOP Limit
НМО	\$0 - \$3,650	\$3,651 to \$6,000	\$6,001 - \$8,300
HMO POS	\$0 - \$3,650 In-network	\$3,651 to \$6,000	\$6,001 - \$8,300 In-network
Local PPO	\$0 - \$3,650 In-network and \$0 - \$5,450 Combined	\$3,651 to \$6,000 In-network and \$3,651 - \$8,950 Combined	\$6,001 - \$8,300 In-network and \$6,001 - \$12,450 Combined
Regional PPO	\$0 - \$3,650 In-network and \$0 - \$5,450 Combined	\$3,651 to \$6,000 In-network and \$3,651 - \$8,950 Combined	\$6,001 - \$8,300 In-network and \$6,001 - \$12,450 Combined
PFFS (full network)	\$0 - \$3,650	\$3,651 to \$6,000	\$6,001 - \$8,300
PFFS (partial network)	\$0 - \$3,650	\$3,651 to \$6,000	\$6,001 - \$8,300
PFFS (non-network)	\$0 - \$3,650	\$3,651 to \$6,000	\$6,001 - \$8,300

In summary, we are finalizing \S 422.100(f)(4)(vi) (proposed in paragraph (f)(4)(vii)) with changes in the transition schedule to calculate annual in-network MOOP limits and modifications to paragraph (f)(4) addressed in this section and section II.A.4. of this FC.

CMS will monitor the penetration rate of beneficiaries with diagnoses of ESRD in MA plans and if the penetration rate ends up being significantly different from Medicare FFS, we will consider future rulemaking to alter the methodology CMS uses to set MOOP limits if there are significant unforeseen impacts or negative consequences that need to be addressed. We also would consider whether additional changes would outweigh the interests of maintaining a settled methodology for the MOOP limits and sufficiently protect enrollees from substantial changes in cost sharing and benefits from one year to the next. Finally, we note that MA organizations can still design a PBP with cost sharing that is actuarially equivalent to cost sharing in Medicare FFS while complying with the MOOP and cost sharing limits in this FC.

Comment: A few commenters made specific requests on how CMS should simplify or otherwise modify the proposed transition of ESRD costs into MOOP limits. A commenter requested CMS enforce the schedule to transition ESRD costs into MOOP limits regardless of any year-over-year changes to the 95th and 85th percentiles for the following reasons: (1) ESRD migration is happening separately from any changes to non-ESRD costs in setting the MOOP limits; and (2) potential delays in the ESRD phase-in schedule could require additional member premium increases for non-ESRD members in order to subsidize ESRD member costs. Another

commenter noted that simplifying the methodology for incorporating the ESRD cost differential would increase transparency and predictability.

Response: Regarding the request to enforce the ESRD cost transition schedule year-overyear regardless of any other considerations, we believe the commenter was specifically referring to the guardrails at proposed $\S 422.100(f)(4)(v)(A)$ and (C) that we proposed to prevent sudden. significant changes to MOOP limits for contract year 2023 and 2024 (or until the end of the ESRD cost transition) if the projections of the 85th or 95th percentile were to shift more than two percentiles within 1 year. We proposed that if the dollar value at the 85th or 95th percentile shifted more than two percentiles during the ESRD cost transition, the MOOP limits would only increase or decrease by 10 percent. The 97th and 93rd percentiles of the contract year 2021 Medicare FFS data projections (based on Medicare FFS data from 2015 – 2019) were \$11,485 and \$6,391 respectively, in comparison to the 95th percentile of \$8,174. The 97th percentile was approximately 40 percent higher than the 95th percentile and the 93rd percentile was approximately 22 percent lower than that the 95th percentile for contract year 2021. In addition, the 87th and 83rd percentiles of the contract year 2021 Medicare FFS data projections (based on Medicare FFS data from 2015 – 2019) were \$3,993 and \$3,162 respectively, in comparison to the 85th percentile of \$3,537. The 87th percentile was approximately 13 percent higher than the 85th percentile and the 83rd percentile was approximately 11 percent lower than that the 85th percentile for contract year 2021. Our proposed guardrails were intended to protect MA enrollees from being potentially subject to a MOOP amount that is substantially different compared to the prior contract year. However, based on historical trends, we do not expect a shift in one year that is outside of the range created by these percentiles. We believe that the guardrails can be simplified while protecting enrollees as intended.

We are modifying the proposed guardrails to use only a 10 percent cap on increases to MOOP limits from the prior year and will apply this guardrail for contract year 2023 and subsequent years at § 422.100(f)(4)(iv) and (v). In essence, we are not finalizing the condition

that the projections of the 85th or 95th percentile must shift more than two percentiles within one year in order to apply a 10 percent change cap to the mandatory and lower MOOP limits. We are also not finalizing the proposal to toll or delay the incorporation of the ESRD cost differential as part of the limits on changes to MOOP limits from year to year. We are finalizing the 10 percent guardrail in paragraphs (f)(4)(iv) and (v) and will apply it during and after the ESRD cost transition. To simplify the regulation text for how CMS calculates the MOOP limits for contract year 2024 and subsequent years, we are also consolidating into one paragraph ((f)(4)(v)(A))rather than two (proposed paragraphs (f)(4)(v)(A) and (C)) the methodology that will apply consistently to both the mandatory and lower MOOP types (with the only difference being the percentile that determines the type of limit). This makes the regulation simpler while providing stability and a measure of predictability for enrollees and MA organizations about the degree of change that may occur in MOOP limits from year to year. As finalized, paragraphs (f)(4)(iv) and (f)(4)(v) provide that the mandatory and lower MOOP limits may only increase by 10 percent; the intermediate MOOP limit will be calculated as the numeric midpoint between the mandatory and lower MOOP limits after application of the 10 percent cap on increases, subject to the clarified rounding rules. By finalizing only the 10 percent cap on increases, we are making the guardrails more definitive and more likely to limit dramatic shifts in annual Medicare FFS data projections that do not quite reach a change that is more than two percentiles from the 95th and 85th percentiles. We believe this is appropriate as the 95th percentile of contract year 2023 Medicare FFS data projections with full incorporation of the ESRD cost differential (based on Medicare FFS data from 2017 - 2021) is \$9,111 and does not reflect a change that is more than two percentiles different than the projected amounts for the prior contract year. Specifically, based on Medicare FFS data from 2016 – 2020, the projected contract year 2022 95th percentile was \$8,468, the 97th percentile was \$11,837, and the 93rd percentile was \$6,631. Using the proposed two percentile requirement, these projections would not trigger CMS to apply the 10 percent cap to calculate the contract year 2023 mandatory MOOP limit because \$9,111 does not

exceed \$11,837. Using the \$9,111 amount without applying the cap on increases would produce a contract year 2023 mandatory MOOP limit of \$8,550, which is approximately 13 percent higher than the contract year 2022 mandatory MOOP limit (\$7,550) after applying the rounding rules and incorporating 70 percent of the ESRD cost differential. In addition, this would increase the intermediate MOOP limit as it is calculated using the numeric midpoint between the mandatory and lower MOOP limits and the total catastrophic (combined) MOOP limits as they are calculated at 1.5 times the in-network amounts. It is likely that significant increases in costs occurring within two percentiles of the prior year's Medicare FFS data projections would circumvent the purpose of our proposed guardrail to provide stability and predictability of MOOP limits from one year to the next. In such a situation, MA enrollees would not be protected from potentially significant increases in MOOP amounts for that contract year. In order to better protect MA enrollees from significant increases in costs for contract year 2023 and future years, we are finalizing the 10 percent cap on increases without the two percentile requirement; application of the 10 percent cap is shown in Tables 2 through 9. In summary, this removal of the two percentile requirement results in a contract year 2023 mandatory MOOP limit that is \$8,300 rather than \$8,550 and an intermediate MOOP limit that is \$6,000 rather than \$6,100. In addition, the increases to the total catastrophic (combined) MOOP mandatory and intermediate MOOP types for contract year 2023 were tempered through application of the final 10 percent cap requirement, with the mandatory limit set at \$12,450 rather than \$12,800 and the intermediate MOOP limit set at \$8,950 rather than \$9,150. With regard to the lower MOOP limit, the contract year 2023 limit compared to the prior contract year reflects an increase less than 10 percent. In addition, the contract year 2023 85th percentile (\$3,772) did not exceed the prior year's 87th percentile (\$4,153), so there is no effect in removing the two-percentile requirement for the lower in-network and total catastrophic (combined) MOOP type for contract year 2023. As shown in Tables 6 through 9, we currently project that the contract year 2024 mandatory MOOP limit will incorporate any remaining difference, to the lower of \$9,130 (a 10

percent increase) or the value at the 95th percentile as projected using the annually updated Medicare FFS data projections.

Regarding the comments about potential increases in MA premiums associated with our proposals to limit increases in the MOOP limits from year to year and to phase-in the ESRD cost differential over a period of time, only 40 percent of the ESRD cost differential was incorporated into the MOOP limits set for contract year 2021 (and maintained for contract year 2022) which is a one year delay in incorporating additional ESRD costs (in comparison to the schedule proposed). Despite this delay and the limited increase in MOOP limits for these contract years during which enrollment of beneficiaries with diagnoses of ESRD continued to increase into the MA program, the weighted average monthly plan premium is continuing to decrease from prior years and the percent of plans offering supplemental benefits or other benefit flexibilities (such as, SSBCI) continues to increase (based on plan bid information for contract year 2022). This suggests that increases in plan premiums or supplemental benefit changes are not occurring on an aggregate level in response to a 1 year delay of incorporating additional ESRD costs into the methodology CMS uses to calculate MOOP limits. We expect this may be a result of market forces and competition. Therefore, we believe that finalizing a 10 percent cap on increases to the MOOP limits from the prior year and its application for the mandatory and intermediate MOOP limits (in-network and combined) using contract year 2023 Medicare FFS data projections (based on Medicare FFS data from 2017 – 2021) will not immediately result in MA plans increasing premiums or reducing benefits. We are finalizing guardrails at § 422.100(f)(4)(iv) and (v) that use this 10 percent cap on increases in the mandatory and lower MOOP limits; this cap will necessarily limit increases in the intermediate MOOP limit and the total catastrophic (combined) MOOP limits as well based on the methodology to calculate those limits.

Therefore, subject to the rounding rules in § 422.100(f)(4)(iii) and the ESRD cost transition schedule in § 422.100(f)(4)(vi), the MOOP limits for 2023 and subsequent years will be calculated as follows:

For contract year 2023 (applying both $\S 422.100(f)(4)(iv)$ and (vi)(A)):

- The mandatory MOOP limit is calculated as \$7,175 (the 95th percentile of projected contract year 2021 Medicare FFS beneficiary out-of-pocket spending for beneficiaries without diagnoses of ESRD) plus 70 percent of the ESRD cost differential unless: the resulting MOOP limit (after application of the rounding rules in paragraph (f)(4)(iii) of this section) reflects an increase greater than 10 percent compared to the mandatory MOOP limit from the prior year, in which case CMS caps the increase to the mandatory MOOP limit by 10 percent of the prior year's MOOP limit.
- The intermediate MOOP limit is calculated as the numeric midpoint between the mandatory and lower MOOP limits (calculated before application of the rounding rules in § 422.100(f)(4)(iii) and after application of the 10 percent cap on increases to the mandatory and lower MOOP limits from the prior year in paragraphs (f)(4)(iv)(A) and (C)).
- The lower MOOP limit is calculated as \$3,360 (the 85th percentile of projected contract year 2021 Medicare FFS beneficiary out-of-pocket spending for beneficiaries without diagnoses of ESRD) plus 70 percent of the ESRD cost differential unless: the resulting MOOP limit (after application of the rounding rules in paragraph (f)(4)(iii) of this section) reflects an increase greater than 10 percent compared to the voluntary MOOP limit from the prior year, in which case CMS caps the increase to the lower MOOP limit by 10 percent of the prior year's MOOP limit.

The MOOP limits for contract year 2024 and subsequent years will be calculated, subject to the rounding rules in paragraph (f)(4)(iii), as follows:

• The mandatory and lower MOOP limits are calculated as the 95th and 85th percentiles of the Medicare FFS data projections if the resulting MOOP limits reflect a decrease or an increase equal to or less than 10 percent compared to each of the prior year's corresponding MOOP limits. If the MOOP limits are not calculated as the 95th and 85th percentiles of the Medicare FFS data projections, CMS increases the prior year's mandatory and lower MOOP

limits by 10 percent annually until the MOOP limits are calculated at the applicable percentile (95th percentile for the mandatory MOOP limit and 85th percentile for the lower MOOP limit) of Medicare FFS data projections. This policy is finalized in paragraph (f)(4)(v)(A).

• The intermediate MOOP type is either maintained at the prior year's limit or if either the mandatory or lower MOOP limit changes from the prior year, updated to the new numeric midpoint between the mandatory and lower MOOP limits (calculated before application of the rounding rules in paragraph (f)(4)(iii) and after application of the 10 percent cap on increases to the mandatory and lower MOOP limits from the prior year in paragraph (f)(4)(v)(A)). This policy is finalized in paragraph (f)(4)(v)(B).

As a result, CMS will distribute significant (that is, more than 10 percent) increases to the mandatory and lower MOOP types over multiple years in order to avoid potential disruption to beneficiaries and plan designs for contract year 2023 and subsequent years. This is generally consistent with our approach in the February 2020 proposed rule of limiting changes in the MOOP limit but, we believe, is a more direct and simpler approach. Based on the contract year 2021 Medicare FFS data projections (based on Medicare FFS data from 2015 – 2019) available at the time of the February 2020 proposed rule, a comparison of 95th percentile data reflected an approximate 14 percent difference (\$8,174 with and without ESRD costs compared to \$7,175 with only non-ESRD costs, respectively). As discussed in the February 2020 proposed rule, distributing a difference in projected costs of this magnitude over multiple years is necessary in order to avoid disruption to beneficiaries. By applying the 10 percent cap, we will ensure changes of a similar magnitude are limited. For example, if the value at the 95th percentile of Medicare FFS data is \$10,049 (meaning a MOOP limit of \$10,050 after application of the rounding rules in paragraph (f)(4)(iii)), and the next year the value at the 95th percentile is projected to be \$11,219 (a rounded MOOP value of \$11,200), there would have been a potential increase of \$1,150 or approximately 11 percent. Under the rules finalized here, the MOOP limit would be increased by only 10 percent, resulting in a mandatory MOOP limit of \$11,050 in the

second year. In the third year, the mandatory MOOP limit would incorporate any remaining difference, to the lower of \$12,150 (a 10 percent increase) or the value at the 95th percentile as projected using the annually updated Medicare FFS data projections. If the 95th percentile for the third year is projected to be \$11,603 (an increase of approximately 5 percent over the prior year), the MOOP limit for that third year would be \$11,600 after application of the rounding rules. By applying the 10 percent cap, we will ensure increases of a similar magnitude are limited. However, the projections for 2024 and subsequent years would be made using annually updated Medicare FFS data projections that are based on data for beneficiaries with and without diagnoses of ESRD.

This 10 percent cap on increases to the MOOP limits provision in § 422.100(f)(4)(iv) and (v) will make sure that, if the projected 95th or 85th percentile substantially increases from one year to the next for contract year 2023 and subsequent years, enrollees are not subject to potentially significant increases in MOOP amounts for that contract year. In addition, by consistently applying the 10 percent guardrail and ESRD cost transition to both the mandatory and lower MOOP limits (which, in turn, determine the intermediate MOOP limit and the total catastrophic MOOP limits), there will be a level of stability and predictability for MA organizations and better protection for MA enrollees. Codifying this rule provides transparency in how CMS will address significant changes in Medicare FFS data projections for contract year 2023 and subsequent years. In addition to these substantive changes, this FC includes clarifying edits. By generally maintaining the proposed limit of a 10 percent increase in comparison to the prior year's MOOP limit amount, we are essentially continuing the ESRD cost transition, but in a limited fashion in order to protect enrollees from potentially significant changes in out-of-pocket costs. As a result, we do not believe these guardrails will directly result in increases in premiums or decreases to supplemental benefits. However, we will consider future rulemaking if there are significant unforeseen changes.

CMS proposed a similar but separate methodology to maintain or update MOOP limits for contract year 2025 or after completion of the ESRD cost transition at proposed § 422.100(f)(4)(vi). Since we are applying the simplified guardrails in paragraph (f)(4)(v) to contract year 2024 and subsequent years, we are not finalizing paragraph (f)(4)(vi) as proposed. Our proposal included similar guardrails for during the ESRD cost transition and after the completion of the ESRD cost transition to protect against potentially disruptive changes to the MOOP limits during and after the ESRD cost transition; this FC is generally consistent with that. In addition, we are not finalizing the requirement that there must be a consistent trend of changes over 3 years of the 85th and 95th percentiles to update the mandatory and lower MOOP limits after the ESRD cost transition is completed (proposed in paragraphs (f)(4)(vi)(A)(2) and (f)(4)(vi)(C)(2)). In the February 2020 proposed rule, we noted that the OACT uses the most recent complete Medicare FFS data to project costs for the applicable year. Specifically, the OACT applies actuarial judgement to create trend factors (that are consistent with the Medicare Trustees Report) to project expected costs (or savings) for the applicable future year, taking into consideration current laws, regulations, and several years of Medicare data in order to determine the cost projections CMS proposed to use to calculate MOOP limits. As a result, the requirement to meet a 3-year trend as proposed is duplicative of the trend factors to an extent and may unnecessarily delay updates to the MOOP limits. In proposing use of a 3-year trend, we intended to base changes in the MOOP limits on a material change. To achieve the goal of updating the MOOP limits when there are material changes to the Medicare FFS data projections, as intended by the February 2020 proposed rule, CMS will instead annually update the MOOP limits to reflect the applicable percentile of Medicare FFS data projections. Small fluctuations in the MOOP limits are likely to be eliminated by application of the rounding rule, so changes in the MOOP limit from year to year will be within these ranges:

- Decreases of \$50 or more, in \$50 increments; or
- Increases of at least \$50 and in increments of \$50 but less than a 10 percent increase.

In summary, § 422.100(f)(4)(iv) and (v) reflect final CMS policies in this FC for 2023 and for subsequent years. We expect that applying the standardized update, as detailed in paragraphs (f)(4)(iv) and (v), will result in MOOP limits that better guard against potentially disruptive annual changes. Therefore, we are finalizing this more streamlined approach, which includes aspects of our proposal, to calculate the mandatory and lower MOOP limits for contract year 2023 and subsequent years.

CMS will annually update the mandatory and lower MOOP limits for the upcoming contract year (subject to the rounding rules at paragraph § 422.100(f)(4)(iii)) to reflect the Medicare FFS data projections of the 85th and 95th percentiles unless either of the resulting MOOP limits reflect an increase greater than 10 percent compared to the same type of MOOP limit from the prior year. If there is a 10 percent or more increase in the dollar value at the applicable percentile, we would cap the increase of the applicable MOOP limit(s) at 10 percent of the prior year's MOOP limit annually, until the MOOP limit(s) reflects the applicable percentile(s). In addition, under finalized paragraph (f)(4)(iv)(B) and (f)(4)(vi)(B), for 2023 and for subsequent years, the intermediate MOOP limit will either be maintained at the prior year's limit, or, if the mandatory or lower MOOP limit changes from the prior year, we will update the intermediate MOOP limit to the new numeric midpoint between the mandatory and lower MOOP limits (calculated before application of the rounding rules in paragraph (f)(4)(iii) and after application of the 10 percent cap on increases to the mandatory and lower MOOP limits from the prior year in paragraphs (f)(4)(iv) and (v)). Application of this methodology for calculating and setting contract year 2023 MOOP limits is reflected in Tables 2 through 5, as described previously in this section.

We included Tables 6 through 9 to illustrate how contract year 2024 MOOP limits would be set using the methodology described in § 422.100(f)(4)(v) and applying the ESRD cost transition and the 10 percent cap on increases to the MOOP limits. Specifically, Tables 6 through 9 illustrate how CMS would calculate contract year 2024 MOOP limits using contract year 2023

Medicare FFS data projections (based on Medicare FFS data from 2017 – 2021) because contract year 2024 projections were not available at the time of this FC. For example, the illustrative contract year 2024 in-network mandatory and lower MOOP limits in Table 6 reflect 100 percent of the ESRD cost differential based on finalized § 422.100(f)(4)(vi)(B). However, other potential outcomes are possible and we expect the final contract year 2024 MOOP limits will be different than the illustrative amounts in Table 9 after updating the calculations to use contract year 2024 Medicare FFS data projections (based on Medicare FFS data from 2018 – 2022).

TABLE 6: CMS CALCULATIONS OF ILLUSTRATIVE CONTRACT YEAR 2024 IN-NETWORK MANDATORY AND LOWER MOOP LIMITS USING CONTRACT YEAR 2023 MEDICARE FFS DATA PROJECTIONS (BASED ON 2017 – 2021 MEDICARE FFS DATA)

Row		Mandatory MOOP	Lower MOOP
Reference	Description	Limit	Limit
A	Contract year 2023 MOOP limit (values from row J in Table 2)	\$8,300.00	\$3,650.00
В	Maximum contract year 2024 MOOP limit per § 422.100(f)(4)(v) (110% of row A)	\$9,130.00	\$4,015.00
С	Medicare FFS percentile in § 422.100(f)(4)	95 th	85 th
D	Unrounded contract year 2024 MOOP limit prior to applying 10% cap on increases per § 422.100(f)(4)(v) and (vi)(B) ¹	\$9,111.00	\$3,772.00
Е	Unrounded contract year 2024 MOOP limit with 10% cap on increases applied (the lesser value comparing row B and row D)	\$9,111.00	\$3,772.00
F	Rounded contract year 2024 MOOP limit per § 422.100(f)(4)(iii) and (v) (row E rounded)	\$9,100.00	\$3,750.00
G	Lowest dollar range of the contract year 2024 MOOP limit per § 422.100(f)(4)(i)	\$6,451.002	\$0.003
Н	Illustrative contract year 2024 MOOP limit dollar ranges per § 422.100(f)(4)(i) through (iii) and (v) through (vi)	\$6,451.00 to \$9,100.00	\$0.00 to \$3,750.00

 $^{^{\}mathrm{I}}$ These amounts are for illustrative purposes only and are the values for contract year 2023 from row D in Table 2 (the unrounded Medicare FFS data projections for the applicable percentile in row C). The projected percentile amounts CMS will use to calculate the final contract year 2024 MOOP limits will be based on Medicare FFS data from 2018 – 2022 and reflect 100 percent of the ESRD Cost Differential per § 422.100(f)(4)(vi)(B).

TABLE 7: CMS CALCULATIONS OF ILLUSTRATIVE CONTRACT YEAR 2024 INNETWORK INTERMEDIATE MOOP LIMIT USING CONTRACT YEAR 2023 MEDICARE FFS DATA PROJECTIONS (BASED ON 2017 – 2021 MEDICARE FFS DATA)

Row		Intermediate MOOP
Reference	Description	Limit
A	Unrounded contract year 2024 mandatory MOOP limit with 10% cap on increases applied	\$9,111.00
	(row E, mandatory MOOP limit column in Table 6)	
В	Unrounded contract year 2024 lower MOOP limit with 10% cap on increases applied (row	\$3,772.00
	E, lower MOOP limit column in Table 6)	
С	Unrounded contract year 2024 intermediate MOOP limit per § 422.100(f)(4)(v) (numeric	\$6,441.50
	midpoint between row A and row B)	
D	Rounded contract year 2023 intermediate MOOP limit (row C rounded per	\$6,450.00
	§ 422.100(f)(4)(iii))	
Е	Lowest dollar range of the contract year 2024 MOOP limit per § 422.100(f)(4)(i)(B)	\$3,751.00*
F	Illustrative contract year 2024 intermediate MOOP limit dollar range per § 422.100(f)(4)(i)	\$3,751.00 to
	through (iii) and (v) through (vi)	\$6,450.00

^{*}The in-network intermediate MOOP limit dollar range begins at the value of the in-network lower MOOP limit from row F in Table 6 plus \$1.00 per § 422.100(f)(4)(i)(B).

TABLE 8: CMS CALCULATIONS OF ILLUSTRATIVE CONTRACT YEAR 2024 COMBINED MOOP LIMITS FOR LPPO AND TOTAL CATASTROPHIC MOOP LIMITS FOR RPPO PLANS USING CONTRACT YEAR 2023 MEDICARE FFS DATA PROJECTIONS (BASED ON 2017 – 2021 MEDICARE FFS DATA)

²The in-network mandatory MOOP limit dollar range begins at the value of the in-network intermediate MOOP limit from row D in Table 7 plus \$1.00 per § 422.100(f)(4)(i)(A).

³The in-network lower MOOP limit dollar range begins at \$0.00 per § 422.100(f)(4)(i)(C).

Row		Mandatory MOOP	Intermediate MOOP	Lower MOOP
Reference	Description	Limit	Limit	Limit
A	Corresponding unrounded in-network MOOP type with 10% cap on increases applied (values from row E in Table 6 and row C in Table 7)	\$9,111.00	\$6,441.50	\$3,772.00
В	Unrounded contract year 2024 combined and total catastrophic MOOP limit per § 422.101(d)(3)(ii) (row A multiplied by 1.5)	\$13,666.50	\$9,662.25	\$5,658.00
С	Rounded contract year 2024 combined and total catastrophic MOOP limit (row B rounded per § 422.100(f)(4)(iii))	\$13,650.00	\$9,650.00	\$5,650.00
D	Lowest dollar range of the contract year 2024 MOOP limit per § 422.101(d)(3)(ii)	\$6,451.001	\$3,751.002	$$0.00^3$
Е	Illustrative contract year 2024 combined and total catastrophic MOOP limit dollar ranges per § 422.101(d)(3)(ii)	\$6,451.00 to \$13,650.00	\$3,751.00 to \$9,650.00	\$0.00 to \$5,650.00

¹The combined and total catastrophic mandatory MOOP limit dollar range begins at the value of the in-network intermediate MOOP limit from row D in Table 7 plus \$1.00 per § 422.101(d)(3)(ii)(A).

TABLE 9: ILLUSTRATIVE CONTRACT YEAR 2024 MOOP LIMITS BY PLAN TYPE

Plan Type	Lower MOOP Limit	Intermediate MOOP Limit	Mandatory MOOP Limit
НМО	\$0 - \$3,750	\$3,751 to \$6,450	\$6,451 - \$9,100
HMO POS	\$0 - \$3,750 In-network	\$3,751 to \$6,450	\$6,451 - \$9,100 In-network
Local PPO	\$0 - \$3,750 In-network and \$0 - \$5,650 Combined	\$3,751 to \$6,450 In-network and \$3,751 - \$9,650 Combined	
Regional PPO		\$3,751 to \$6,450 In-network and	\$6,451 - \$9,100 In-network and
PFFS (full network)	\$0 - \$3,750	\$3,751 to \$6,450	\$6,451 - \$9,100
PFFS (partial network)	\$0 - \$3,750	\$3,751 to \$6,450	\$6,451 - \$9,100
PFFS (non-network)	\$0 - \$3,750	\$3,751 to \$6,450	\$6,451 - \$9,100

Some other potential outcomes of how CMS may annually update MOOP limits for 2024 and for subsequent years, subject to the rounding rules in paragraph (f)(4)(iii) and the ESRD cost transition in paragraph (f)(4)(vi), may include:

- Maintaining the contract year 2024 MOOP limits for contract year 2025 if the 95th and 85th percentiles of contract year 2025 Medicare FFS data projections result in values equivalent to the MOOP limits in effect for the prior contract year after applying the rounding rules at § 422.100(f)(4)(iii).
- Calculating updated MOOP limits for contract year 2026 (after the contract year 2024 MOOP limits were maintained for contract year 2025) if the 95th and 85th percentiles of contract

²The combined and total catastrophic intermediate MOOP limit dollar range begins at the value of the in-network lower MOOP limit from row F in Table 6 plus \$1.00 per § 422.101(d)(3)(ii)(B).

³The combined and total catastrophic lower MOOP limit dollar range begins at \$0.00 per § 422.101(d)(3)(ii)(C).

year 2026 Medicare FFS data projections result in increases of 3 percent and 5 percent, respectively, from the MOOP limits in effect for the prior contract year.

• Increasing the prior year's mandatory MOOP limit by 10 percent and increasing the prior year's lower MOOP limit by 8 percent (and calculating the intermediate MOOP limit per the regulation text) for contract year 2025 if the 95th and 85th percentiles of contract year 2025 Medicare FFS data projections result in increases of 16 and 8 percent, respectively, from the MOOP limits in effect for the prior contract year.

We reiterate that, as finalized in § 422.100(f)(7)(i), CMS will use generally accepted actuarial principles and practices in projecting the beneficiary out of pocket costs using updated Medicare FFS data each year to calculate MOOP limits in accordance with paragraph (f)(4) and (5) and § 422.101(d)(2) and (d)(3). In addition, we may explain the calculations CMS made to apply the regulations through the subregulatory process finalized in paragraph (f)(7)(iii). Tables 2 through 4 illustrate how the methodology for setting the MOOP limits for has been applied for contract year 2023 MOOP limits. Because this FC is adopting the specific MOOP limits for contract year 2023, as shown in Table 5, the requirement for a subregulatory notice and comment process will begin with the calculation of the 2024 MOOP limits under the rules finalized in §§ 422.100(f)(4) and (f)(5) and 422.101(d)(2) and (d)(3).

Comment: A few commenters were concerned that MA provider network instability or weak dialysis networks in combination with higher MOOP limits would discourage beneficiaries with diagnoses of ESRD from enrolling in MA plans. Concerns about the number of dialysis providers in an MA plan network appear tied to the MA and cost plan network adequacy proposal from the February 2020 proposed rule that was finalized in the June 2020 final rule. Similarly, another commenter was concerned about the combination of ESRD payment rates, MOOP limits, and network adequacy standards creating disincentives for beneficiaries with diagnoses of ESRD from enrolling in MA plans. In addition, a commenter requested that CMS ensure beneficiaries with diagnoses of ESRD are properly informed about the adequacy of MA

plan networks (in addition to out-of-pocket costs as discussed in section II.A.4. of this FC) to assist them in making health care coverage choices.

Response: We do not believe that CMS's network adequacy requirements and ESRD payment rates by themselves or in combination with the MOOP limit provision will discourage beneficiaries with diagnoses of ESRD from enrolling in MA plans. We direct commenters to the Calendar Year 2021 and 2022 Rate Announcements at https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents for finalized policies on ESRD payment for contract year 2021 and 2022. As mentioned in the Calendar Year 2021 Rate Announcement, we will continue to analyze and consider whether, consistent with the statutory provisions for setting ESRD rates in section 1853(a)(1)(H) of the Act, any refinements to the methodology may be warranted in future years. We also direct commenters to the June 2020 final rule (85 FR 33796) for how CMS finalized policies related to network adequacy (section V.A. of the June 2020 final rule) and note that MA plans and cost plans are required to provide medically necessary services for all enrollees and that the regulations regarding network adequacy standards do not limit application of this requirement. In addition, MA organizations must maintain a network of contracted providers that is sufficient to provide adequate access to covered services to meet the needs of the population served and is consistent with the prevailing community pattern of health care delivery in the areas where the network is being offered per § 422.112. Importantly, the regulations at § 422.112(a) provide a critical beneficiary protection (including when a provider or facility specialty type is not subject to the network evaluation standards in § 422.116) that access to providers at in-network cost sharing must be provided by the MA organization if the MA plan's network providers are unavailable or inadequate to furnish medically necessary benefits for an enrollee. This critical beneficiary protection ensures that MA enrollees have similar reasonable access to providers and facilities for covered benefits as beneficiaries in Medicare FFS. Therefore, we believe that MA plans will continue to provide adequate access to dialysis providers and the network adequacy requirements will not discourage beneficiaries with diagnoses of ESRD from enrolling in MA plans. The ESRD payment rates, CMS's network adequacy requirements, and the MOOP limit do not provide an incentive for MA organizations to discriminate against beneficiaries with chronic conditions, including diagnoses of ESRD.

If beneficiaries believe that an MA organization is not providing adequate access to services, complaints may be submitted online or by calling 1-800-MEDICARE. CMS monitors and investigates complaints related to plan coverage and CMS caseworkers assist in the resolution of issues with the MA organizations. CMS may take compliance or enforcement actions against an MA organization for failing to meet any contract or regulatory requirements, such as providing adequate access to medically necessary services, as warranted. In addition, enrollees who have complaints about their plan have the right to file a grievance under § 422.564 and, if they believe that benefits have been improperly denied, file an appeal under the appeal rules in §§ 422.562 through 422.619.

In addition, we believe provider networks and the plan's established MOOP amount are not the only factors beneficiaries consider when choosing a health plan. Enrollees may continue to consider a number of factors in relation to their unique healthcare needs and financial situation, such as perception of brand, premium, plan type, benefits, cost sharing, quality ratings, provider network, and the MOOP amount when choosing a health care plan²¹. This information will continue to be available to beneficiaries as they review their MA plan options for the upcoming contract year. Beneficiaries can use Medicare Plan Finder (MPF), provider network information, and other communications materials in determining which plan options available to them (such as the MA program, Medicare FFS, and Medigap) best meet their healthcare needs and financial situation.

d. Out-of-Scope Comments

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²¹ Adam Barnhart, Julia M. Friedman, and Peter T. Kissinger, Milliman, "Star Rating Changes: How Medicare Advantage Plans React," October 2020 https://us.milliman.com/en/insight/Star-rating-changes-How-Medicare-Advantage-plans-react.

Comment: Many commenters also provided a wide range of feedback that was outside of the scope of the changes proposed to §§ 422.100(f) and 422.101(d) for the MOOP limits, including requests for CMS to change ESRD payments for MA plans in addition to, or in place of, transitioning ESRD costs into MOOP limits; commenters stated these payment changes would mitigate the costs for MA plans and keep MA program costs low for beneficiaries. These commenters were concerned that payment changes were needed in order to ensure MA plans and ultimately providers have the resources needed to treat this population of chronically ill patients, support MA plans in covering the higher medical costs for beneficiaries with diagnoses of ESRD, and prevent detrimental changes to the number and scope of plans offered, premiums, cost sharing, and supplemental benefits. A commenter was concerned the ESRD payment amounts might limit MA plan options. Similarly, some commenters suggested that we adjust MA payment rates for ESRD beneficiaries receiving dialysis to reflect the impact of MOOP limits.

In addition, a few commenters were concerned that the estimate of kidney acquisition costs, which are carved out of MA payment rates, was inflated and tied that to the proposed MOOP limits. A commenter was specifically concerned that an inflated estimate of kidney acquisition costs, combined with the proposed MOOP limits, could lead to reductions in benefits and result in adverse selection for plans that may attract higher numbers of enrollees with diagnoses of ESRD (such as through lower MOOP limits and cost sharing structures). Other out-of-scope comments included suggestions to modify the MOOP limit to include the Part D prescription drug program and to change the total beneficiary cost (TBC) evaluation that CMS uses (under § 422.256(a)) each year to identify MA bids that include potentially significant increases in enrollee costs or decreases in enrollee benefits.

Response: While we appreciate the comments, ensuring payments to MA plans capture the cost of enrollees with diagnoses of ESRD and the development of MA capitation rates (which must exclude kidney acquisition costs pursuant to section 1853(k) and (n) of the Act) is not within the scope of the proposal to adopt a methodology for calculating MOOP limits.

Further, we do not find the specific suggestions to modify MA payments (including adjusting payment rates for beneficiaries receiving dialysis to reflect the impact of MOOP limits as well as rate adjustments to be made instead of factoring in the ESRD cost differential) to be consistent with our interpretation of section 1853 of the Act as a whole, which is that CMS should more closely align MA payment rates with FFS costs. We also do not find the suggestions consistent with the statutory provisions for ESRD payment policies. In accordance with section 1853(b) of the Act, CMS addresses the methodology for developing the MA (including ESRD) capitation rates and payment policies in the Advance Notice and Rate Announcement for each contract year.²² Comments were submitted and addressed in the CY 2021 and CY 2022 Rate Announcements. Similar to comments regarding the accuracy in calculating the kidney acquisition cost, the methodology used by CMS and the amount of payment to MA plans are addressed by CMS in the annual Rate Announcement. We direct readers to the annual Advance Notice and Rate Announcement documents for a more detailed discussion of these issues. We also direct commenters to the June 2020 final rule (85 FR 33796) for how CMS finalized policies related to kidney acquisition costs (sections III.B. and III.C. of the June 2020 final rule) and ESRD enrollment (section III.A. of the June 2020 final rule). To the extent that consideration of how enrollees with diagnoses of ESRD will incur more costs, including out-of-pocket expenses, is related to calculating the MOOP limits, we have addressed those issues in section II.A.4.c. of this FC in response to other comments.

Finally, the MOOP limit is one of a number of factors that CMS takes under consideration in setting the TBC standard on an annual basis. For example, we also consider benefit and payment policies and technical out-of-pocket cost (OOPC) model changes. The TBC evaluation process is distinct and separate from calculating MOOP and cost sharing limits. We direct commenters to the HPMS memorandum titled "Final Contract Year 2021 Part C Benefits

²² Advance Notice and Rate Announcement documents are available at: https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents.

Review and Evaluation," issued April 8, 2020, for TBC requirements finalized for contract year 2021 and the HPMS memorandum titled "Final Contract Year 2022 Part C Benefits Review and Evaluation," issued May 20, 2021, for TBC requirements finalized for contract year 2022²³. CMS released an HPMS memorandum titled "Preliminary Contract Year 2023 Part C Benefits Review and Evaluation" on March 3, 2022 (with a comment period) that includes potential changes to the TBC threshold for contract year 2023. CMS will also consider soliciting comment on how CMS sets the TBC threshold for contract year 2024 and future years, if necessary.

5. Final Decision

CMS received feedback from 27 commenters pertaining to the MOOP limit proposal, with the majority reflecting support for, or requests for modifications to, the proposed amendments at §§ 422.100(f)(4) and (5) and 422.101(d)(2) and (3) to: (1) calculate three innetwork and out-of-network MOOP limits for local and regional MA plans; (2) transition the ESRD cost differential (that is, data regarding the out-of-pocket costs of beneficiaries who have diagnoses of ESRD) into the Medicare FFS data used to calculate MOOP limits; and (3) calculate MOOP limits during and after completion of the transition schedule. We thank commenters for their feedback and helping to inform our final policy concerning MOOP limits. CMS intends to track several measures of plan benefit design to monitor the potential impact of the polices adopted in this FC, such as: (1) percent of plans offering lower MOOP limits; (2) percent of plans that use copayments rather than coinsurance in their plan designs; (3) percent of plans that establish the highest allowable cost sharing for each service category (and/or the average or median cost sharing for each service category as a direct year over year comparison); (4) percent of plans with zero premium; and (5) the average number of plan options. CMS may consider additional changes to the methodology for calculating MOOP limits in future rulemaking if this FC results in unforeseen negative consequences, does not encourage favorable

²³ These HPMS memoranda may be accessed through the HHS guidance repository at: HHS Guidance Submissions | Guidance Portal and individuals and organizations may request placement on the HPMS listserv at https://hpms.cms.gov/app/ng/home/.

benefit designs for enrollees, or does not increase access to plan offerings with lower or intermediate MOOP amounts and cost sharing that is lower or comparable when compared to existing benefit packages.

After careful consideration of all the comments we received, and for the reasons set forth in the February 2020 proposed rule and in our responses to the related comments discussed previously, we are finalizing amendments §§ 422.100(f)(4) and (5) and 422.101(d)(2) and (3) as proposed, with some modification. These new MOOP provisions are applicable for coverage beginning January 1, 2023 and later. We will therefore use these rules and the final contract year 2023 MOOP limits in Table 5 to evaluate MA bids submissions due the first Monday in June (June 6, 2022) for the 2023 contract year. We will also use these rules to evaluate MA bid submissions for subsequent contract years going forward. In summary, the proposed changes are finalized substantially as proposed but with the following modifications from the proposal:

- Adding descriptive headings to $\S 422.100(f)(1) (9)$ to orient the reader to the content in each paragraph.
- Applying the methodology in the amendments to §§ 422.100(f)(4) and (5) and 422.101(d)(2) and (3) beginning on or after January 1, 2023 instead of January 1, 2022.
- Revisions in §§ 422.100(f)(4) and (5) and 422.101(d)(2) and (3) to use consistent language in regulation text when referring to: (1) plan MOOP amounts established by MA organizations and MOOP limits calculated by CMS; (2) in-network, combined, catastrophic, and total catastrophic MOOP limits, amounts, or types; and (3) the Medicare FFS data projections CMS uses in calculating MOOP and cost sharing limits.
- Revising introductory language in § 422.100(f)(4) for clarity and to: (1) retain how MA local plans, as defined in § 422.2, must have an enrollee in-network maximum out-of-pocket amount for basic benefits before January 1, 2023 that is no greater than the annual limit calculated by CMS using Medicare FFS data projections; and (2) codify current policy that the in-network MOOP limits apply to PFFS plans for all covered basic benefits.

- Revising § 422.100(f)(4)(i) to address: (1) that CMS will calculate three MOOP limits; (2) the addition of a definition for the term "Medicare FFS data projections"; and (3) how the MOOP limits are based on the Medicare FFS data projections.
- Adding § 422.100(f)(4)(i)(A) (C) to specify: (1) the dollar ranges of the three innetwork MOOP types; (2) the range of the mandatory MOOP limit begins one dollar above the intermediate MOOP limit; and (3) the range of the intermediate MOOP limit begins one dollar above the lower MOOP limit.
- Revisions in § 422.100(f)(4)(ii) to: (1) clarify that the ranges specified in paragraphs (f)(4)(i)(A) through (C) are dollar ranges for each MOOP type; and (2) add references to §§ 422.101(d) and 422.113 because the MOOP types are referenced in those sections.
- Removing § 422.100(f)(4)(ii)(A) (C), as this information is finalized with clarifications in paragraphs (f)(4)(i)(A) (C).
- Revisions in § 422.100(f)(4)(iv) to: (1) address how CMS will calculate MOOP limits for 2023, including incorporation of 70 percent of the ESRD cost differential in the data used for calculating the MOOP limits; and (2) apply a 10 percent cap on increases to the MOOP limits from the prior year.
- Revisions in § 422.100(f)(4)(iv)(B) to provide that the numeric midpoint is calculated from the mandatory and lower MOOP limits before rounding and after application of the 10 percent cap on increases to the mandatory and lower MOOP limits from the prior year.
- Revisions in § 422.100(f)(4)(v) to: (1) update the applicable dates (to 2024 and subsequent years); and (2) update the reference to the ESRD cost transition to paragraph (f)(4)(vi)(B).
- Revisions in § 422.100(f)(4)(v)(A) to: (1) apply that paragraph to calculate both the mandatory and lower MOOP limits to make the regulation text concise and ensure consistency in the methodology; (2) replace the two-percentile guardrail with a 10 percent cap on increases to

the MOOP limits from the prior year; and (3) to include clarifying edits because the proposal to delay the ESRD cost differential transition is not being finalized.

- Revisions in § 422.100(f)(4)(v)(B) to: (1) clarify that the numeric midpoint is calculated between the mandatory and lower MOOP limits if either limit changes from the prior year; (2) avoid double rounding in the calculations of the intermediate MOOP limit; and (3) calculate the numeric midpoint after application of the 10 percent cap on increases to the mandatory and lower MOOP limits from the prior year.
- Removing § 422.100(f)(4)(v)(C) as the methodology CMS will use to calculate the lower MOOP limit for contract year 2024 and subsequent years is addressed in paragraph (f)(4)(v)(A).
- Removing proposed \S 422.100(f)(4)(vi) as the methodology for how CMS calculates MOOP limits for 2025 and subsequent years is now addressed in paragraph (f)(4)(v).
- Finalizing the proposed ESRD cost differential transition (proposed at § 422.100(f)(4)(vii)) in paragraph (f)(4)(vi) with revisions to: (1) clarify that the definition of "ESRD cost differential" is used for purposes of the ESRD cost transition methodology to calculate annual MOOP limits; (2) correct and update the definition of the ESRD cost differential by using the new defined term of Medicare FFS data projections and identifying the specific Medicare FFS percentiles that CMS will use for each MOOP type; (3) decrease the percentage of ESRD cost differential to incorporate for 2023 (70 percent instead of 80 percent); and (4) finalize the substance of proposed paragraph (f)(4)(vii)(C) in paragraph (f)(4)(vi)(B) and apply it to 2024 and subsequent years.
- Revisions in § 422.100(f)(5) to clarify that the MOOP limits specified in paragraph (f)(4) apply to in-network providers.
- Revisions in § 422.100(f)(5)(i) to: (1) clarify that the combined MOOP is applied to MA enrollees (rather than beneficiaries); and (2) refer to § 422.101(d)(3) to encompass the addition of dollar ranges for the total catastrophic (MOOP) limits.

- Revisions in § 422.100(f)(5)(iii) to clarify that the MA organization's responsibility to track out-of-pocket spending applies to the combined MOOP amount.
- Finalizing new § 422.100(f)(7)(i) to: (1) clarify that CMS will use generally accepted actuarial principles and practices in making the projections and calculations used in the methodologies described in §§ 422.100(f)(4), (f)(5), (f)(6), (f)(7)(ii), (f)(8), and (j) and 422.101(d)(2) and (d)(3) to calculate the MOOP limits; and (2) provide examples of the types of approaches and data CMS may consider. This provision and paragraphs (f)(7)(i)(B) (C) are also applicable to the cost sharing standards addressed in paragraph (f)(6) and (j) and a more complete discussion of these applications is available in section II.B. of this FC.
- Finalizing new § 422.100(f)(7)(iii) to: (1) codify a specific rule, beginning with contract year 2024, requiring CMS to issue subregulatory guidance prior to bid submission that specifies the MOOP limits and cost sharing standards CMS sets for the upcoming year to allow sufficient time for MA organizations to prepare and submit plan bids; and (2) provide a public comment period on the projected MOOP limits and cost sharing standards for the upcoming contract year, unless a public comment period is impracticable, unnecessary, or contrary to the public interest.
- Revisions in § 422.101(d)(2) to specify the requirements related to establishing a catastrophic MOOP amount for MA regional plans.
- Revisions in § 422.101(d)(2)(i) to require MA regional plans to establish a catastrophic enrollee MOOP amount for basic benefits that are furnished by in-network providers that is consistent with § 422.100(f)(4).
- Revisions in § 422.101(d)(2)(ii) to: (1) remove repetitive references to the requirement that MA organizations are required to track out-of-pocket spending and alert enrollees and contracted providers when the MOOP amount is reached; and (2) clarify that MA regional plans must have the same MOOP type for the catastrophic MOOP (in-network) limit and total catastrophic (combined in-network and out-of-network expenditures) limit.

- Revisions in the introductory language of § 422.101(d)(3) to clarify that the total catastrophic MOOP amount encompasses the combined in-network and out-of-network expenditures and that this MOOP amount is applied to MA enrollees.
- Revisions in § 422.101(d)(3)(i) to: (1) avoid repetitive text in the regulation; and (2) clarify the reference to paragraph (d)(2) applies to the catastrophic limit.
- Revisions in § 422.101(d)(3)(ii) to: (1) avoid double rounding in the calculations of the total catastrophic MOOP limits; (2) calculate the total catastrophic MOOP limits using the mandatory and lower MOOP limits after application of the 10 percent cap on increases from the prior year; and (3) add new paragraphs (d)(3)(ii)(A), (B), and (C) to provide the dollar ranges for each type of total catastrophic MOOP limit (mandatory, intermediate, and lower) for purposes of paragraph (d) and § 422.100(f) and (j).
- Removing proposed § 422.101(d)(3)(iii) and revising to: (1) remove repetitive references to the requirement that MA organizations are required to track out-of-pocket spending and alert enrollees and contracted providers when the MOOP is reached; and (2) reference the total catastrophic MOOP dollar ranges specified in paragraph (d)(3)(ii) for purposes of paragraph (d) and §§ 422.100(f)(6), (j)(1), and 422.113(b)(2)(v) as those sections apply certain flexibilities depending on the MOOP type established.
- Adding various minor technical and grammatical changes from the proposed regulation text at §§ 422.100(f)(4) and (5) and 422.101(d)(2) and (3) to ensure clarity and avoid repetitive text in the regulations.

Finally, in addition to the authority outlined in the February 2020 proposed rule for these MOOP limits, section 1854(a)(5) and (6) of the Act provide that CMS is not obligated to accept every bid submitted and may negotiate with MA organizations regarding the bid, including benefits. Under section 1854(a)(5)(C)(ii) of the Act, CMS is authorized to deny a plan bid if the bid proposes too significant an increase in enrollee costs or decrease in benefits from one plan year to the next. While the rules adopted here do not limit our negotiation authority (§ 422.256), they

provide minimum standards for an acceptable benefit design for CMS to apply in reviewing and evaluating bids in addition to establishing important protections to ensure that enrollees with high health care costs are not discouraged from enrolling in MA plans.

B. Service Category Cost Sharing Limits for Medicare Parts A and B Services and Per Member

Per Month Actuarial Equivalence Cost Sharing (§§ 422.100 and 422.113)

Section 1852 of the Act imposes a number of requirements that apply to the cost sharing and benefit design of MA plans. First, section 1852(a)(1)(B)(i) of the Act provides that the MA organization must cover, subject to limited exclusions, the benefits under Parts A and B (that is, basic benefits as defined in § 422.100(c)) with cost sharing that does not exceed or is at least actuarially equivalent to cost sharing in original Medicare; this is repeated in a bid requirement under section 1854(e)(4) of the Act. We have addressed and implemented that requirement in several regulations, including §§ 422.101(e)(2), 422.102(a)(4), and 422.254(b)(4). Second, section 1852(a)(1)(B)(iii) and (iv) of the Act also imposes particular constraints on the cost sharing for specific benefits, which have been implemented in § 422.100(i) for MA plans and extended to cost plans under § 417.454(e); the statute authorizes CMS to add to the list of items and services for which MA cost sharing may not exceed the cost sharing levels in original Medicare. Relatedly, we have codified a requirement in § 422.100(k) that MA plans must cover original Medicare-covered preventive services (as defined in §410.152(1)) without cost sharing when the services are provided in-network; the same restriction is applied to cost plans under § 417.454(d). Third, section 1852(b)(1) of the Act prohibits discrimination by MA organizations on the basis of health status-related factors and directs that CMS may not approve an MA plan if CMS determines that the design of the plan and its benefits are likely to substantially discourage enrollment by certain MA eligible individuals. The requirements under §§ 422.100(f)(4) and (5) that impose Maximum Out-of-Pocket (MOOP) limits on MA local plans are based on this antidiscrimination provision and designed to prohibit discrimination against or discouragement of enrollment by beneficiaries with high health care needs. In addition, the MOOP requirements

under §§ 422.101(d)(2) and (3) implement the statutory catastrophic limits imposed on regional MA plans under section 1858(b) of the Act. Section 422.100(f)(6) provides that cost sharing must not be discriminatory. Calculating limits on cost sharing for covered services is an important way to ensure that the cost sharing aspect of an MA plan design does not discriminate against or discourage enrollment of beneficiaries who have high health care needs. CMS issued annual limits on cost sharing for covered services and guidance addressing discriminatory cost sharing, as applied to specific benefits and to categories of benefits, in the annual Call Letters issued prior to 2020²⁴ and in bidding instructions. In addition, Chapter 4²⁵ of the Medicare Managed Care Manual (MMCM) has contained long-standing polices regarding discriminatory cost sharing based on the requirements under § 422.100(f).

Currently, CMS annually analyzes Medicare program data to interpret and apply the various cost sharing limits from these authorities and to publish guidance on MA cost sharing limits. The relevant Medicare data included in this analysis are the most recent Medicare fee-for-service (FFS) data, including cost and utilization data, and MA patient utilization information from MA encounter data. CMS sets cost sharing limits based on analyses of and projections from this data and then reviews cost sharing established by MA organizations to determine compliance with the cost sharing limits and requirements established in the statute and regulations, as interpreted and implemented in sub-regulatory guidance, including Chapter 4 from the MMCM. The cost sharing limits set by CMS reflect a combination of outpatient and professional visits and inpatient utilization scenarios based on the lengths of stays typically used by average to sicker Medicare patients. CMS uses multiple inpatient utilization scenarios to guard against MA organizations setting inpatient cost sharing amounts in a manner that is

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²⁴ See the HPMS memorandum titled "Final Contract Year 2021 Part C Benefits Review and Evaluation," issued April 8, 2020, for information on MOOP and cost sharing limits for contract year 2021 and the HPMS memorandum titled "Final Contract Year 2022 Part C Benefits Review and Evaluation," issued May 20, 2021, for information on MOOP and cost sharing limits for contract year 2022.

²⁵ Chapter 4 of the MMMCM can be accessed at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c04.pdf

potentially discriminatory. CMS also sets review parameters for frequently used Medicare professional services, such as primary and specialty care services.

CMS proposed to codify our current and longstanding practice and methodology for interpreting and applying the limits on MA cost sharing, with some modifications. In addition, CMS proposed to add categories of services to the regulation requiring MA cost sharing be no greater than that in original Medicare. Our proposal as a whole, in combination with the MOOP proposal in section VI.A. of the February 2020 proposed rule, aimed to provide MA organizations incentives to offer plans with favorable benefit designs for beneficiaries. As noted in the February 2020 proposed rule, organizations must also comply with applicable Federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, sex (sexual orientation and gender identity), age, disability, including section 1557 of the Affordable Care Act, title VI of the Civil Rights Act of 1964, section 504 of the Rehabilitation Act of 1973, and the Age Discrimination Act of 1975. None of the proposals in the February 2020 proposed rule limited application of such anti-discrimination requirements.

In the February 2020 proposed rule, CMS explained that in developing and applying the reviews of MA cost sharing for 2020 and prior years²⁶, we exclude the costs for individuals with diagnoses of ESRD from the Medicare FFS data used. We explained the exclusion of costs for these individuals is because of the pre-2021 restrictions on when and how Medicare beneficiaries with diagnoses of ESRD could enroll in an MA plan under section 1851(a) of the Act. In the February 2020 proposed rule, we stated that in contract year 2018, 0.6 percent of the MA enrollee population, or approximately 121,000 beneficiaries, have diagnoses of ESRD. This statistic was based on the statutory definition of ESRD and CMS data. Using more recent enrollment data, the number of beneficiaries enrolled in MA in contract year 2018 with

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²⁶ After publication of the February 2020 proposed rule, CMS announced that it would take the Medicare FFS costs of beneficiaries with diagnoses of ESRD into account in developing MOOP limits and cost sharing limits for 2021 and 2022. See the HPMS memorandum titled "Final Contract Year 2021 Part C Benefits Review and Evaluation," issued April 8, 2020, for information on MOOP and cost sharing limits for contract year 2021 and HPMS memorandum titled "Final Contract Year 2022 Part C Benefits Review and Evaluation," issued May 20, 2021, for information on MOOP and cost sharing limits for contract year 2022.

diagnoses of ESRD is lower than previously stated, approximately 120,100 (which does not impact the 0.6 percent of the MA enrollee population figure)²⁷. As discussed in more detail in section III.A. of the June 2020 final rule (85 FR 33796), section 17006 of the 21st Century Cures Act amended the Medicare statute to allow Medicare beneficiaries with diagnoses of ESRD to enroll in MA plans beginning in contract year 2021. CMS expected this change would result in Medicare beneficiaries with diagnoses of ESRD beginning to transition to, or choosing, MA plans in greater numbers than they did before contract year 2021. As discussed in the February 2020 proposed rule, the OACT expected ESRD enrollment in MA plans to increase by 83,000 as a result of the 21st Century Cures Act provision. The OACT assumed the increase would be phased in over 6 years, with half of those beneficiaries (41,500) enrolling during 2021. Given the potential increase in enrollment of beneficiaries with diagnoses of ESRD in MA plans, the OACT has conducted another analysis to determine the impact of including all costs incurred by beneficiaries with diagnoses of ESRD into the Medicare FFS data CMS uses to project future out-of-pocket expenditures to calculate cost sharing standards and limits. Based on the most recent analyses and projections, adding in ESRD costs (that is, projected out-of-pocket costs for beneficiaries with diagnoses of ESRD) affects MA cost sharing limits for inpatient hospital acute length of stay scenarios, with the longer length of stay scenarios being the most affected. As discussed in section VI.A. of the February 2020 proposed rule, CMS proposed a schedule for incorporating use of the most recent, complete Medicare FFS data for beneficiaries with diagnoses of ESRD into the data used to set MOOP limits. (Section II.A. of this FC addresses that proposal.) CMS made a similar proposal to codify, with some updates and changes, the current process for calculating non-discriminatory cost sharing limits and to incorporate out-ofpocket expenditures for beneficiaries with diagnoses of ESRD. CMS also proposed to codify the

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²⁷ The Fiscal Year President's Budgets may be accessed at https://www.govinfo.gov/app/collection/BUDGET/ and the annual Advance Notice and Rate Announcements may be accessed at https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents. In addition, see page 14 from the 2020 Rate Notice and Final Call Letter, retrieved from https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2020.pdf.

methodology used to set the standards for MA cost sharing for professional services and for inpatient hospital acute and psychiatric services at § 422.100(f)(6) and to require MA plans to have cost sharing that does not exceed the standards set each year using the methodology in paragraph (f)(6). As explained in the February 2020 proposed rule (and reflected in the proposed regulation text), the limits in proposed § 422.100(f)(6) would be in addition to other limits on cost sharing that apply to MA plans. CMS also proposed, at § 422.100(j), that MA plans must not impose cost sharing that exceeds original Medicare for certain specific benefits and for certain categories of benefits on a per member per month actuarially equivalent basis. The proposal also included specific cost sharing requirements for emergency/post-stabilization services and urgently needed services, proposed in § 422.113(b)(2)(v) and (vi).

We explained in the February 2020 proposed rule how CMS is committed to encouraging plan offerings with favorable MOOP and cost sharing limits. Based on that, CMS proposed to modify the regulations at §§ 422.100(f)(6) and 422.113(b)(2)(v) and (vi) to establish a range of cost sharing limits for basic benefits furnished on an in-network basis based on the MOOP limit established by the MA plan. We explained that providing MA organizations with greater flexibility to set cost sharing based on different MOOP limits should incentivize MA organizations to create favorable benefit designs for MA enrollees.

In addition, CMS proposed amending §§ 422.100(f)(6) and (j) and 422.113(b)(2) to implement safeguards to ensure MA enrollees are not subject to discriminatory benefits or discriminatory costs for basic benefits. These proposed safeguards included codifying a long-standing interpretation of the current anti-discrimination provision of section 1852(b)(1) that payment of less than 50 percent of the total MA plan financial liability discriminates against enrollees who need those services. Specifically, CMS proposed to codify in § 422.100(f)(6)(i)(A) that MA plans may not pay less than 50 percent of the total MA plan financial liability, regardless of the MOOP limit established, for basic benefits that are provided in-network and out-of-network that are not explicitly addressed in the cost sharing standards at paragraph (f)(6).

We noted in the February 2020 proposed rule that, under current policy and guidance²⁸, copayments are expected to reflect specific benefits identified within the plan benefit package (PBP) service category or a reasonable group of benefits or services. Organizations may design their plan benefits as they see fit so long as they satisfy Medicare coverage requirements, including applicable MA regulations. MA organizations typically offer benefits with lower cost sharing amounts than the annual limits published by CMS; we believe this is due to multiple factors, including the principles and incentives inherent in managed care, effective negotiations between organizations and providers, and market competition.

1. General Non-Discriminatory Cost Sharing Limits (§ 422.100(f)(6))

CMS proposed to codify in § 422.100(f)(6) a set of general rules for cost sharing for basic benefits. The term "basic benefits," as defined in § 422.100(c), means items and services (other than hospice care and, beginning 2021, coverage for organ acquisitions for kidney transplants) for which benefits are available under Parts A and B of Medicare and including additional telehealth benefits offered consistent with the requirements at § 422.135. We proposed that the rules in paragraph (f)(6) must be followed by MA plans in addition to other regulatory and statutory requirements for cost sharing. MA organizations have the option to charge either coinsurance or a copayment for most service categories, which we aimed to make clear in the proposed regulation text. Under our proposal, the MA plan would be prohibited from exceeding the coinsurance or copayment limit for service category standards set by CMS using the various rules in paragraph (f)(6) and (j). In addition, after publication of the February 2020 proposed rule, the Families First Coronavirus Response Act (Pub. L. 116-127) amended section 1852 of the Act to prohibit MA plans from charging enrollees higher cost sharing than is charged under original Medicare for COVID-19 testing and testing-related services identified in section 1833(cc)(1) for which payment would be payable under a specified outpatient payment provision

²⁸ See page 180 in the 2020 Rate Notice and Final Call Letter, retrieved from https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2020.pdf.

described in section 1833(cc)(2) during the period from March 18, 2020, through to the end of the emergency period described in section 1135(g)(1)(B) (namely, the COVID-19 public health emergency). The Coronavirus Aid, Relief, and Economic Security Act (Pub. L. 116-136) amended section 1852(a)(1)(B) to require MA plans have cost sharing that does not exceed cost sharing in Original Medicare for a COVID-19 vaccine and its administration described in section 1861(s)(10)(A) of the Act.

CMS proposed to codify our long-standing interpretation and implementation of the antidiscrimination provisions (including section 1852(b)(1) of the Act) that payment of less than 50 percent of the total MA plan financial liability discriminates against enrollees who have significant health care needs and discourages enrollment in the plan by such beneficiaries. We stated how we recognize that it is difficult to set a cost sharing limit for every possible benefit and that this catch-all rule, which has been long-standing policy used in our review of bids, is an important beneficiary protection. We proposed that this rule would apply regardless of the MOOP limit established and regardless of whether the basic benefit is furnished in-network or out-of-network, to protect beneficiaries regardless of the MA plan they choose. As used in the proposed regulation text, the term "total MA plan financial liability" meant the total payment paid and includes both the enrollee cost sharing and the amount paid by the MA organization. Specifically, CMS proposed to codify at § 422.100(f)(6)(i) that MA plans may not pay less than 50 percent of the total MA plan financial liability, regardless of the MOOP limit established, for in-network benefits and out-of-network benefits for which a cost sharing limit is not otherwise specified in proposed paragraph (f)(6), inclusive of basic benefits. In order to clarify this policy, we also proposed in paragraphs (f)(6)(i)(B) and (C) how this rule would apply when coinsurance or copayment structures are used: (1) if the MA plan uses copayments, the copayment for an outof-network benefit cannot exceed 50 percent of the average Medicare FFS allowable amount for that service area and the copayment for in-network benefits cannot exceed 50 percent of the average contracted rate of that benefit (that is, the PBP service category level or for a reasonable

group of benefits or services covered under the plan); and (2) if the MA plan uses coinsurance, then the coinsurance cannot exceed 50 percent.

CMS also proposed general rules to govern how CMS would set copayment limits. This included proposed § 422.100(f)(6)(ii)(A) which provided that CMS rounds amounts to the nearest whole \$5 increment for professional services copayments and nearest whole \$1 for inpatient acute and psychiatric and skilled nursing facility copayments. Our proposal at paragraph (f)(6)(ii)(B) provided that for all cases in which the copayment limit is projected to be exactly between two increments, CMS rounds to the lower dollar amount. This rounding rule would codify, for the most part, current policy, but with slight modification to protect beneficiaries from higher increases in costs by rounding down whenever possible.

In proposed § 422.100(f)(6)(iii), CMS proposed to codify rules to give MA plans flexibility in setting cost sharing for professional services, including primary care services, physician specialist services, partial hospitalization, and rehabilitation services. The proposed flexibility is, in many respects, the same as the flexibility we currently provide for MA plans that use the lower, voluntary MOOP limit, but with modifications to account for our proposal in section VI.A. of the February 2020 proposed rule which proposed the setting of three MOOP limits each year. This included new paragraph (f)(6)(iii)(A) to provide that an MA plan may not establish cost sharing amounts that exceed the limits under paragraph (f)(6)(iii) for basic benefits that are professional services furnished in-network (that is, by contracted providers). In addition, CMS proposed new paragraph (f)(6)(iii)(B) to specify the data that CMS would use in applying the methodology in paragraph (f)(6)(iii) to set the cost sharing limits for professional services. As proposed, the specific data would be projections of out-of-pocket costs representing beneficiaries with and without diagnoses of ESRD based on the most recent, complete Medicare FFS data. Finally, CMS proposed new paragraph (f)(6)(iii)(C) to outline the method for setting the cost sharing limits for professional services each year and to clarify that the resulting limits (specified as dollar amounts) are subject to the rounding rules in paragraph (f)(6)(ii). CMS

explained the cost sharing limits would vary based on the type of MOOP limit used by the MA plan as follows:

- Mandatory MOOP limit: 30 percent coinsurance or actuarially equivalent copayment values. The MA plan must not pay less than 70 percent of the total MA plan financial liability.
- Intermediate MOOP limit: 40 percent coinsurance or actuarially equivalent copayment values. The MA plan must not pay less than 60 percent of the total MA plan financial liability.
- Lower MOOP limit: 50 percent coinsurance or actuarially equivalent copayment values. The MA plan must not pay less than 50 percent of the total MA plan financial liability.

Under the proposal, an MA plan must pay no less than a specific percentage of the total financial liability for professional services to align with the range of flexibility each MOOP limit provides. We explained that our proposal was intended to ensure that there is a clear increase in an MA organization's financial responsibility for professional services if the MA plan uses a mandatory MOOP limit, rather than a lower or intermediate MOOP limit. We arrived at the specified percentages by assigning the highest coinsurance amount that was not discriminatory (50 percent) to the lowest MOOP limit, and assigning 30 percent coinsurance (which is most closely related to copayment limits from prior contract years) to the mandatory MOOP limit, to balance the incentives for each type of MOOP limit. We proposed the midpoint (40 percent) for the intermediate MOOP limit. We explained that these coinsurance percentages would result in reasonable differences between expected copayment limits for each of the MOOP limits. Overall, our proposal aimed to prevent discrimination against the enrollees with high health needs for the covered services by setting these cost sharing limits to cap the amount of financial responsibility for professional services the MA organization can transfer to enrollees. To set the actuarially equivalent values for the copayment limits based on the regulation text each year, we stated that CMS would calculate copayment limits that are approximately equal to the identified coinsurance percentage limit based on the OACT's projections of the most recent, complete

Medicare FFS data that includes 100 percent of the out-of-pocket costs representing all beneficiaries with and without diagnoses of ESRD.

CMS proposed to base the approximate actuarially equivalent copayment limits for primary care, physician specialties, mental health specialty services, and physical and speech therapy on the most recent, complete Medicare FFS average cost data (including 100 percent of the out-of-pocket costs incurred by beneficiaries with diagnoses of ESRD), weighted by utilization for the applicable provider specialty types for each service category. We stated that using an average that is weighted by specialty type utilization is consistent with developing an actuarially equivalent copayment for the coinsurance percentage specified in proposed § 422.100(f)(6)(iii). We solicited comment on whether our regulation text should be further revised on this point. In the preamble of the February 2020 proposed rule, we listed the applicable provider specialty types we would use in this analysis:

- Primary Care: Family Practice; General Practice; Internal Medicine
- Physician Specialties: Cardiology; Geriatrics; Gastroenterology; Nephrology;
 Otolaryngology (ENT)
- Mental Health Specialty Services: Clinical Psychologist; Licensed Clinical Social
 Worker; Psychiatry
- Physical and Speech Therapy: Physical Medicine and Rehabilitation; Speech-language Pathologists

In addition to these categories, we proposed to base the approximate actuarially equivalent copayment limits for psychiatric services, occupational therapy, and chiropractic care on the most recent, complete Medicare FFS cost data from a single, most applicable provider specialty: respectively, Psychiatry, Occupational Therapist, and Chiropractor. We solicited comment on whether other provider specialty types should inform our proposed actuarially equivalent copayment limits for the various professional services. Table 5 (Illustrative Contract Year 2022 In-Network Service Category Cost Sharing Limits) from the February 2020 proposed

rule (85 FR 9086-9087) provided an illustration of potential cost sharing limits for contract year 2022 based on projections of the Medicare FFS cost data from 2015 - 2019 for professional services, emergency/post-stabilization services, and urgently needed services.

We also solicited comment on whether to require additional regulation text to address combining or bundling of cost sharing. CMS has previously issued guidance in Chapter 4, section 50.1, "Guidance on Acceptable Cost-sharing²⁹," of the MMCM that cost sharing should appear to MA enrollees consistent with MA disclosure requirements at § 422.111(b)(2). Section 422.111(b)(2) requires MA plans to clearly and accurately disclose benefits and cost sharing. We explained in the February 2020 proposed rule that MA plans must identify (and charge) the enrollee's entire cost sharing responsibility as a single copay (if using copayment rather than coinsurance) even if the MA plan has differential cost sharing that varies by facility setting or contracted arrangements that involve separate payments to facilities (or settings) and other providers. As discussed in the February 2020 proposed rule, we are aware that a facility or another health care delivery setting may charge an amount separate from that charged by the health care provider who actually furnishes covered services. In the February 2020 proposed rule, we clarified that those separate fees should be combined (bundled) into the cost sharing amount for that particular place of service and be clearly reflected as a total copayment in beneficiary communication and marketing materials. We noted that we believe this current guidance is an appropriate interpretation of § 422.111, but solicited comment on codifying it. 2. Cost Sharing Limits for Inpatient Hospital Acute and Psychiatric Services $(\S 422.100(f)(6)(iv))$

As discussed in the February 2020 proposed rule, since contract year 2011, CMS has set cost sharing limits for certain inpatient length of stay scenarios based on a percentage of

²⁹Chapter 4, Section 50.1 of the MMMCM can be accessed at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c04.pdf.

estimated Medicare FFS cost sharing projected to the applicable contract year. We explained the current process and proposed to codify continued use of it with some modifications.

We stated in the February 2020 proposed rule that the OACT conducts an annual analysis of the most recent, complete Medicare FFS data, and uses that data to project costs for the Part A deductible and Part B costs based on the length of stay scenarios and the setting of the inpatient stay (acute or psychiatric), to help determine the inpatient hospital acute and psychiatric cost sharing limit amounts. CMS compares the cost sharing for an MA enrollee, under the plan design for each bid, to the projected Medicare FFS cost sharing in each scenario; for MA plans with the mandatory MOOP limit, the cost sharing limit is 100 percent of the Medicare FFS cost sharing for the applicable scenario and for MA plans using the lower, voluntary MOOP limit, it is 125 percent of the Medicare FFS cost sharing. If an MA plan's cost sharing exceeds the applicable limit for any of the length of stay scenarios, CMS considers the MA plan's cost sharing as discriminatory under current § 422.100 and does not approve that plan benefit package. CMS proposed new § 422.100(f)(6)(iv)(A) through (D) to codify this long-standing policy for the cost sharing established by an MA plan for inpatient acute and psychiatric services, with modifications to incorporate cost sharing expenditures for beneficiaries with diagnoses of ESRD in setting the limits and to set a limit for MA plans that use the intermediate MOOP limit. Proposed paragraph (f)(6)(iv)(A) required an MA plan to have cost sharing for inpatient hospital acute and psychiatric benefits that does not exceed the limits set in paragraph (f)(6)(iv). Our proposal aimed to provide transparency on how CMS will set the cost sharing thresholds with which MA organizations must comply for inpatient hospital acute and psychiatric benefits. We proposed that during our review of bids, we would evaluate the MA cost sharing included in plan bids to determine compliance with the cost sharing limits adopted in the regulation.

We proposed to add a 3-day length of stay scenario for acute stays and an 8-day length of stay scenario for psychiatric care to those used under our current policy; these proposed scenarios were based on Medicare FFS data and informed by patient utilization information from

MA encounter data. As a result, proposed § 422.100(f)(6)(iv)(B) specified the seven inpatient stay scenarios (current and new) for which cost sharing would apply under original Medicare and that would be used to set the MA cost sharing limits. The inpatient hospital acute stay scenarios are for 3 days, 6 days, 10 days, and 60 days and the psychiatric inpatient hospital stay scenarios are for 8 days, 15 days, and 60 days. Many of these same scenarios were described in the contract year 2020 Call Letter and in previous years.

Under our proposal, cost sharing limits for each of the seven inpatient hospital length of stay scenarios would incorporate the projected Medicare FFS inpatient Part A deductible and Part B professional costs. We explained that under our proposal, plans could vary cost sharing for different admitting health conditions, providers, or services provided, but overall benefit cost sharing must satisfy the limits established by CMS. Proposed § 422.100(f)(6)(iv)(C) described the data CMS would use for calculating the Medicare FFS out-of-pocket costs for each scenario. Under the proposal, CMS would use projected out-of-pocket costs and utilization data based on the most recent Medicare FFS data that factors in out-of-pocket costs incurred by beneficiaries with diagnoses of ESRD on the transition schedule we proposed in paragraph (f)(4)(vii)(A) through (D) and could also use patient utilization information from MA encounter data. In addition, for purposes of setting these cost sharing limits, the February 2020 proposed rule provided that the Medicare FFS data that factors in the ESRD cost differential would not include the exceptions for tolling the scheduled transition that were proposed for the MOOP limit calculations (in proposed paragraphs (f)(4)(v)(A) and (C)).

As discussed in the February 2020 proposed rule, the OACT conducted an analysis to help determine the impact of including all costs incurred by beneficiaries with diagnoses of ESRD into the most recent Medicare FFS data projections used to calculate cost sharing standards. This analysis found adding in related ESRD costs affects inpatient hospital acute cost sharing limits but that adding in those costs did not impact inpatient hospital psychiatric standards based on projections of Medicare FFS data available at the time of writing the

February 2020 proposed rule. Based on this, we proposed to update the methodology to consider ESRD costs in setting all inpatient hospital acute and psychiatric standards. Specifically, CMS proposed to integrate approximately 60 percent of the difference between Medicare FFS costs incurred by all beneficiaries (including those with diagnoses of ESRD) and the costs excluding beneficiaries with diagnoses of ESRD into the data used to set the inpatient hospital acute and psychiatric cost sharing limits for contract year 2022. After contract year 2022, CMS proposed to incorporate an additional 20 percent of costs incurred by beneficiaries with diagnoses of ESRD each year until contract year 2024, when CMS would integrate 100 percent of the costs incurred by beneficiaries with diagnoses of ESRD into the most recent, complete Medicare FFS data that is used to determine inpatient hospital acute and psychiatric cost sharing limits. This was the same schedule proposed to transition ESRD costs into MOOP limit calculations so we used a cross-reference in the proposed regulation text to avoid repetitive regulation text.

Finally, at § 422.100(f)(6)(iv)(D), CMS proposed specific cost sharing limits for inpatient acute and psychiatric stays that are tied to the type of MOOP limit used by the MA plan. The proposed limits were stated as percentages of the FFS costs for each length of stay scenario (based on original Medicare cost sharing for a new benefit period):

- Mandatory MOOP limit: cost sharing must not exceed 100 percent of estimated
 Medicare Fee-for-Service cost sharing, including the Part A deductible and related Part B costs.
- Intermediate MOOP limit: cost sharing must not exceed the numeric mid-point between the cost sharing limits for the mandatory and lower MOOP limits.
- Lower MOOP limit: cost sharing must not exceed 125 percent of estimated Medicare Fee-for-Service cost sharing, including the Part A deductible and related Part B costs. For inpatient acute 60-day length of stays, we proposed that MA plans that establish a lower MOOP limit would have the flexibility to set cost sharing above 125 percent of estimated Medicare Fee-for-Service cost sharing as long as the total cost sharing for the inpatient benefit does not exceed

the MOOP limit or cost sharing for those benefits in original Medicare on a per member per month actuarially equivalent basis.

We proposed to use the same percentage of estimated Medicare FFS cost sharing for the mandatory and lower MOOP limits (100 percent and 125 percent respectively) as under current policy to determine inpatient hospital acute and psychiatric cost sharing limits. Using the rule proposed in § 422.100(f)(6)(ii)(A), all inpatient hospital acute and psychiatric cost sharing limits would be rounded to the nearest or lower whole \$1 increment. As discussed in the February 2020 proposed rule, our proposal for limits on the cost sharing for inpatient acute and psychiatric services aligned with our current practice (with some modifications, as discussed). We explained that would provide benefit design stability for MA plans.

The February 2020 proposed rule stated that CMS would continue to publish acceptable inpatient hospital acute and psychiatric cost sharing limits and a description of how the regulation standard is applied (that is, the methodology used) through subregulatory means, such as a Health Plan Management System (HPMS) memoranda, issued prior to bid submission each year. We solicited comment on whether to include additional regulation text to establish when information would be published for plans.

The February 2020 proposed rule included Table 4 (Illustrative Example of Cost Sharing Limits Based on Current Medicare FFS Data for Inpatient Hospital Acute 10-Day Length of Stay Scenario), to provide an illustrative example of the cost sharing limits for the 10-day length of stay scenario (an inpatient hospital acute stay); the illustration was developed using 2015 - 2019 data projected to contract years 2022 through 2024 (85 FR 9082). We explained that the limits were illustrations and that the actual cost sharing limits set for future years could change, based on updated projections and Medicare FFS cost sharing requirements. We also explained in more detail how the proposed methodology was applied to illustrate a contract year 2022 cost sharing amount in Table 4.

We also included Table 5 (Illustrative Contract Year 2022 In-Network Service Category Cost Sharing Limits) in the February 2020 proposed rule to illustrate the potential impact of our proposals for other in-network service categories (85 FR 9086 through 9087). The February 2020 proposed rule Table 5 included projections of potential inpatient hospital acute and psychiatric cost sharing limits based on the methodology we proposed in § 422.100(f)(6)(iv). As explained in the February 2020 proposed rule, we expect the cost sharing limits for inpatient services for future years would be different from the illustrations in the February 2020 proposed rule due to updated projections using Medicare FFS data.

CMS requested comments and suggestions on its proposed cost sharing standards. We also requested comment on whether additional regulation text or restructuring of § 422.100(f)(6)(iv) was needed to achieve CMS's goal of providing additional transparency on how CMS will: (1) develop the seven length of stay scenarios for inpatient hospital acute and psychiatric services; (2) transition ESRD costs into inpatient hospital acute and psychiatric limit calculations; and (3) calculate inpatient hospital acute and psychiatric limits after the ESRD cost transition is complete.

3. Basic Benefits for Skilled Nursing Facilities (SNFs), Outpatient, and Professional Services Subject to Cost Sharing Limits (§ 422.100(j))

CMS proposed to codify and adopt specific cost sharing limits for certain benefits (by service and by category of services) that are based on a comparison to the cost sharing applicable in the Medicare FFS program. We relied on both section 1852(a)(1)(B)(iv)(VII)³⁰ and section 1852(b) of the Act to propose codifying the current policy and adding new limits. Section 1852(a)(1)(B)(iv)(VII) of the Act explicitly authorizes the Secretary to identify services that the Secretary determines appropriate (including services that the Secretary determines require a high

³⁰ Section 1852(a)(1)(B)(iv)(IV), as cited in the February 2020 proposed rule, was re-designated to section (a)(1)(B)(iv)(VII) pursuant to amendments to section 1852 of the Act made by the Families First Coronavirus Response Act (P.L. 116-127) and the CARES Act (P.L. 116-136) regarding coverage of COVID-19 testing, testing-related services, and vaccination.

level of predictability and transparency for beneficiaries) to be subject to a cost sharing limit that is tied to the cost sharing imposed for those services under original Medicare. In addition, we have relied on how higher cost sharing for these benefits discriminates against the enrollees who need these services in setting additional cost sharing limits in the past. We believe that charging higher cost sharing for specific services discriminates against and discourages enrollment by beneficiaries with a health status that requires those services. We further rely on sections 1856(b) and 1857(e) of the Act, which authorize CMS to set implementing standards for Part C and adopt additional requirements as necessary, appropriate and not inconsistent with Part C, to the extent necessary to set these additional cost sharing protections for enrollees. As discussed extensively in this FC, setting standards for cost sharing limits and codifying the methodology serves important program purposes and goals for the MA program.

a. Range of Cost Sharing Limits for Certain Outpatient and Professional Services(§ 422.100(f)(6)(iii))

CMS proposed to modify the regulation at § 422.100(f)(6) to establish a range of cost sharing limits based upon the MOOP limit established by the MA plan for basic benefits (as defined in § 422.100(c)(1)) offered on an in-network basis. The proposal was intended to provide MA organizations with benefit design flexibilities while balancing the incentives for each MOOP type. As discussed in the February 2020 proposed rule, this proposal aligned with the long-standing policy of affording MA plans greater flexibility in establishing Parts A and B cost sharing when the MA plan adopts a lower, voluntary MOOP amount.

CMS proposed to add § 422.100(f)(6)(iii) to specify that for basic benefits that are for professional services furnished in-network, MA plans may have greater flexibility in setting cost sharing based on the MOOP limit they establish. This proposal addressed the type of data used to set cost sharing limits for those professional services and proposed paragraphs (f)(6)(iii)(C)(1), (2), and (3) specified the maximum cost sharing limit based on the MOOP limit established by the MA plan. In addition to those cost sharing limits, CMS proposed to amend § 422.100(j) to

impose cost sharing limits for specific benefits and specific categories of benefits that are based on the cost sharing used in original Medicare. Our proposal for paragraph (j) also considered the MOOP type used by an MA plan to grant additional cost sharing flexibility to MA plans with regard to specific services. As a whole, our proposal would apply multiple standards to the cost sharing for professional services and outpatient benefits. In the February 2020 proposed rule, Table 5 (Illustrative Contract Year 2022 In-Network Service Category Cost Sharing Limits) illustrated the application of the proposed copayment limits to in-network cost sharing for basic benefits, using the most recent Medicare FFS data projections available at the time of the February 2020 proposed rule (that is, 2015 - 2019 data) (85 FR 9086 through 9087).

As discussed in the February 2020 proposed rule, CMS will monitor copayment amounts and coinsurance percentages during our annual review of plan cost sharing. Copayments are for specific benefits identified within the PBP service category or a reasonable group of benefits or services covered by the plan. Some PBP service categories may identify specific benefits for which a unique copayment would apply (for example, PBP service category 7a includes "primary care services"), while other categories may include a variety of services with different levels of costs which may reasonably have a range of copayments based on groups of similar services (for example, PBP service category 15 includes "Part B drugs – other" which covers a wide range of products and costs). We noted that MA plans may establish one cost sharing amount for multiple visits provided during an episode of care (for example, several sessions of cardiac rehabilitation) as long as the overall (or total) cost sharing amount satisfies CMS standards. Based on the amendments CMS proposed for §§ 422.100(f)(6), 422.100(j), and 422.113(b)(2)(v) and (vi), we clarified that if finalized, bids for the upcoming year to which the proposed rules would apply must reflect enrollee cost sharing for in-network services no greater than the coinsurance levels set in or the copayments amounts calculated using those regulations. We confirmed that, under our proposal, MA organizations would still have the option to charge either coinsurance or a copayment for most service category benefits. We also noted that

although MA plans have the flexibility to establish cost sharing amounts as copayments or coinsurance, MA plans should keep in mind, when designing their cost sharing, that enrollees generally find copayment amounts more predictable and less confusing than coinsurance³¹. b. Emergency/Post-Stabilization Services and Urgently Needed Services (§ 422.113(b)(2)(v) and (vi))

Currently, § 422.113(b)(2)(v) requires MA plans to charge cost sharing for emergency department services that does not exceed the lesser of: (1) an amount CMS sets annually; or (2) the plan's cost sharing for the services if they were obtained through the MA plan's network. After explaining that applying a specific dollar limit for cost sharing for emergency and poststabilization services would be more appropriate than a methodology for changing the cost sharing limit for those services, we proposed to revise the existing rules for the cost sharing limits for emergency and post-stabilization services and to codify a new rule for cost sharing limits for urgently needed services. CMS proposed, at paragraph (b)(2)(v), that the MA organization is financially responsible for emergency and urgently needed services with a dollar limit on emergency/post-stabilization services costs for enrollees that is the lower of-

- The cost sharing established by the MA plan if the emergency/post-stabilization services were provided through the MA organization; or
- A maximum cost sharing limit permitted per visit that corresponds to the MA plan MOOP limit as follows:
 - o \$115 for MA plans with a mandatory MOOP limit.
 - o \$130 for MA plans with an intermediate MOOP limit.
 - o \$150 for MA plans with a lower MOOP limit.

³¹ Loewenstein G, Friedman JY, McGill B, Ahmad S, Linck S, Sinkula S, Beshears J, J.Choi J, Kolstad J, Laibson D, Madrian BC, List JA, Volpp KG. "Consumers' misunderstanding of health insurance". Journal of Health Economics 2013;32(5):850-862, Retrieved from: https://scholar.harvard.edu/laibson/publications/consumers-

misunderstanding-health-insurance

As discussed in the February 2020 proposed rule, the proposed limits were based on analyses of Medicare FFS costs that showed shifts in payment trends that may affect emergency/post-stabilization services costs more so than urgently needed services. The proposed dollar limits were based on the projected median total allowed amount for emergency services (including visit and related procedure costs) using the most recent Medicare FFS data available at the time, which included 100 percent of the out-of-pocket costs incurred by all beneficiaries, both with and without diagnoses of ESRD. We arrived at the proposed cost sharing limits for an MA plan with a mandatory MOOP limit and an MA plan with a lower MOOP limit by taking the dollar figures that are 15 percent and 20 percent of that median cost, rounded to the nearest whole \$5 increment. The proposed maximum cost sharing limits for MA plans with an intermediate MOOP limit was based on the numeric midpoint of the related cost sharing limits for MA plans with mandatory and lower MOOP limits, rounded to the nearest whole \$5 increment. In addition, CMS proposed clarifying updates to the language at § 422.113(b)(2)(v) to note that the cost sharing limits for emergency services include post-stabilization service costs. For urgently needed services, CMS proposed that the same cost sharing limits for professional services under § 422.100 apply to urgently needed services, regardless whether those urgently needed services are furnished in-network or out-of-network. We did not propose any changes to § 422.113 regarding the MA organization's obligations to cover and pay for emergency/poststabilization services and urgently needed services but only to codify specific cost sharing limits for those services. As noted in the February 2020 proposed rule, CMS intends to monitor trends and consider updating cost sharing limits for both urgently needed services and emergency/poststabilization services in future rulemaking based on emerging trends.

c. Services No Greater Than Original Medicare (§ 422.100(j)(1))

Section 1852(a)(1)(B) of the Act specifies that MA plans may not charge enrollees higher cost sharing than is charged under original Medicare for chemotherapy administration services (which we have implemented as including Part B – chemotherapy/radiation drugs integral to the

treatment regimen), skilled nursing care, and renal dialysis services. This provision is currently reflected in §§ 417.454(e) (for cost plans) and 422.100(j) (for MA plans). The statute provides authority for CMS to require cost sharing that does not exceed cost sharing in the FFS Medicare program for additional Medicare-covered services. As noted elsewhere, section 1852(b) of the Act also prohibits plan designs that have the effect of discriminating against or discouraging enrollment by beneficiaries based on their health needs; we rely on this authority and sections 1856(b) and 1857(e) of the Act, which authorize CMS to set implementing standards for Part C and adopt additional requirements as necessary, appropriate and not inconsistent with Part C, to the extent necessary to set these additional cost sharing protections for enrollees. CMS proposed to restructure paragraph (j) and codify additional cost sharing limits for other services. We clarified that under our proposal cost sharing standards for cost plans will remain the same.

In our current interpretation and application of this requirement for skilled nursing care, MA plans that establish the higher, mandatory MOOP limit must establish \$0 per-day cost sharing for the first 20 days of a SNF stay and the per-day cost sharing for days 21 through 100 must not be greater than the original Medicare SNF amount. We proposed at § 422.100(j)(1)(iii) that, beginning in contract year 2022, the current rule for MA plans that use the higher, mandatory MOOP limit would remain the same and that limited cost sharing for the first 20 days of SNF would be permitted for MA plans that establish either the lower or intermediate MOOP limit.

In addition, CMS proposed to add the following services to the requirement that cost sharing charged by an MA plan may not exceed cost sharing required under original Medicare: (1) home health services (as defined in section 1861(m) of the Act) for MA plans that establish a mandatory or intermediate MOOP limit; and (2) durable medical equipment (DME). For home health services, we also proposed that when the MA plan establishes the lower MOOP limit, the MA plan may have cost sharing up to 20 percent, or an actuarially equivalent copayment, of the total MA plan financial liability. Our proposal would prohibit the DME per-item or service cost

sharing from being greater than original Medicare cost sharing for MA plans that establish a mandatory MOOP limit. For MA plans that establish a lower or intermediate MOOP limit, our proposal was that total cost sharing for all DME PBP service categories combined would be required to be equal or less than original Medicare cost sharing on a per member per month actuarially equivalent basis, but such MA plans would be permitted to establish cost sharing for specific service categories of DME that exceed the cost sharing under original Medicare as long as it complies with other CMS cost sharing requirements. In order to codify these changes at § 422.100(j), we proposed to reorganize that paragraph with new text at paragraph (j)(1) to provide that for the basic benefits specified, an MA plan may not establish in-network cost sharing that exceeds the cost sharing required under original Medicare.

d. In-Network Service Category Cost Sharing Requirements

We included Table 5 (Illustrative Contract Year 2022 In-Network Service Category Cost Sharing Limits) in the February 2020 proposed rule to provide examples of cost sharing limits for contract year 2022 based on projections of the most recent Medicare FFS data available at the time of the February 2020 proposed rule (2015 – 2019 data) and using the proposed methodology to set the various cost sharing limits specified as proposed §§ 422.100(f)(6), 422.100(j) and 422.113(b)(2)(v) and (vi). We noted these were only projections of potential cost sharing limits for contract year 2022 to illustrate the impact of the methodology. We stated that our proposed standards and cost sharing limits would continue to be inclusive of applicable service category deductibles, copayments and coinsurance, but do not include plan level deductibles. We proposed to update the cost sharing limits on an annual basis based on the final regulations. We noted our intention to apply the revised regulations each year to calculate the amounts that would be the copayment limits unless otherwise stated and that we would publish the annual limits with a description of how the regulation standard is applied (that is, the methodology used) prior to bid submission each year, such as through HPMS memoranda. We proposed to use projections of the most recent, complete Medicare FFS data that include 100

percent of ESRD costs to set the amounts for copayment limits, that is the actuarially equivalent amount of the coinsurance limits proposed in paragraph (f)(6), versus a transition of ESRD costs over time; there were no significant differences in the resulting cost sharing amounts when including ESRD for any of the physician specialties based on projections of the most recent Medicare FFS from the OACT.

In the February 2020 proposed rule, Table 5 (Illustrative Contract Year 2022 In-Network Service Category Cost Sharing Limits) did not include approximate actuarially equivalent copayment limits for some services: cardiac rehabilitation, intensive cardiac rehabilitation, pulmonary rehabilitation, supervised exercise therapy (SET) for symptomatic peripheral artery disease (PAD), partial hospitalization, home health, therapeutic radiological services, DME, dialysis, Part B Drugs Chemotherapy/Radiation Drugs, and "Part B Drugs – Other". As discussed in the February 2020 proposed rule, we found these categories are subject to a higher variation in cost or unique provider contracting arrangements, which would potentially make using Medicare FFS average or median cost data less suitable for developing a standardized actuarially equivalent copayment value at this time. Accordingly, in order to monitor and enforce compliance with these cost sharing requirements when the copayment is based on an analysis of the contracted rates the MA plan uses for in-network services, CMS noted that MA organizations may be required to provide information to CMS demonstrating how plan cost sharing complies with the regulation standards proposed in § 422.100(f)(6). We solicited comment whether an explicit regulatory provision should be added to require MA organizations to demonstrate compliance with these standards upon request by CMS; such demonstration would include providing CMS with information substantiating the contracted rates for basic benefits that are professional services for which CMS has not calculated an approximate actuarially equivalent copayment limit, and illustrating how the MA organization determined its cost sharing amounts.

As discussed in the February 2020 proposed rule, MA organizations with plan benefit designs that use a coinsurance or copayment amount for which we did not propose to publish a

specific cost sharing threshold (for example, coinsurance for inpatient or copayment for durable medical equipment), must maintain documentation that clearly demonstrates how the coinsurance or copayment amount satisfies the regulatory requirements for each applicable plan. This is consistent with existing MA program monitoring and oversight for MA organizations to be able to demonstrate compliance with applicable program requirements. Cost sharing and other plan design elements remain subject to § 422.100(f)(2), which prohibits MA plans from designing benefits to discriminate against beneficiaries, promote discrimination, discourage enrollment or encourage disenrollment, steer subsets of Medicare beneficiaries to particular MA plans, or inhibit access to services. This documentation may be used by CMS during bid review as well as to address issues concerning beneficiary appeals, complaints, and/or to conduct general oversight activities. In addition, MA plans are required to attest when they submit their bid(s) that their benefits will be offered in accordance with all applicable Medicare program authorizing statutes and regulations.

4. Per Member Per Month Actuarial Equivalent (AE) Cost Sharing Limits For Basic Benefits (§ 422.100(j)(2))

As discussed in the February 2020 proposed rule, under the statute and regulations, an MA plan's total cost sharing for Parts A and B services (excluding hospice services and kidney acquisition costs and including additional telehealth benefits) must not exceed cost sharing for those services in Medicare FFS on an actuarially equivalent basis and must not be discriminatory. In order to ensure that cost sharing is consistent with both §§ 422.254(b)(4), 422.100(f)(2), and current 422.100(f)(6), CMS has also historically evaluated cost sharing limits on a per member per month actuarially equivalent basis for the following service categories: Inpatient hospital, SNF, DME, and Part B drugs.

Proposed § 422.100(j)(2) required that total cost sharing for all basic benefits covered by an MA plan, excluding out-of-network benefits covered by a regional MA plan, not exceed cost sharing for those benefits in original Medicare on a per member per month actuarially equivalent

basis. We explained that the provision implements section 1852(a)(1)(B) of the Act and the carve out of out-of-network benefits covered by a regional MA plan is to be consistent with section 1852(a)(1)(B)(ii) of the Act. As noted elsewhere, section 1852(b) of the Act also prohibits plan designs that have the effect of discriminating against or discouraging enrollment by beneficiaries based on their health needs. We explained in the February 2020 proposed rule that our proposals were based on this authority and sections 1856(b) and 1857(e) of the Act, which authorize CMS to set implementing standards for Part C and adopt additional requirements as appropriate and not inconsistent with Part C, to the extent necessary. CMS also proposed to codify, in §422.100(j)(2)(i), our existing policy regarding the specific service categories for which an MA plan must not exceed the cost sharing in original Medicare on a per member per month actuarially equivalent basis. The services we proposed for this rule are consistent with long-standing policy and were: (1) inpatient hospital acute and psychiatric services, defined as services provided during a covered stay in an inpatient facility during the period for which cost sharing would apply under original Medicare; (2) DME; (3) drugs and biologics covered under Part B of original Medicare (including both chemotherapy/radiation drugs and other drugs covered under Part B); and (4) skilled nursing care, defined as services provided during a covered stay in a SNF during the period for which cost sharing would apply under original Medicare.

As discussed in the February 2020 proposed rule, we believe our proposals would ensure that MA plans that have greater cost sharing flexibility in these categories are not designing benefits in a way that discriminates against enrollees with health status factors and conditions that require the services in § 422.100(j)(2)(i). Further, we noted that limiting cost sharing in this way will ensure that enrollees with certain conditions, or who are high utilizers of these basic benefits, are not discouraged from enrolling in MA plans because of higher cost sharing on necessary services. We noted that setting copayment limits through quantitative formulas (such as those used for our inpatient hospital acute and psychiatric standards) may be less appropriate

for some categories, like DME and Part B drugs, and that it may be better to evaluate cost sharing for these service categories on an aggregate service category basis to determine whether they are discriminatory. These categories include items or services that significantly vary in cost or may be subject to provider contracting arrangements that make it difficult for CMS to calculate a specific copayment amount for the category as a whole, as opposed to specific items and benefits.

CMS also proposed, at § 422.100(j)(2)(ii), to extend flexibility for MA plans when evaluating actuarial equivalent cost sharing limits for those service categories to the extent that the per member per month cost sharing limit is actuarially justifiable based on generally accepted actuarial principles and supporting documentation included in the bid, provided that the cost sharing for specific services otherwise satisfies published cost sharing standards. The proposed exception would apply in limited situations, such as when the MA plan uses capitated arrangements with provider groups, when the MA organization operates its own facilities, or other unique arrangements. This flexibility would be consistent with long-standing policy and practice.

Overall, our proposal was aimed to describe how CMS would determine whether specific cost sharing is discriminatory and to set standards and thresholds above which CMS believes cost sharing is discriminatory as well as to implement specific statutory authority regarding cost sharing for basic benefits in an MA plan as compared to original Medicare. Similar to our current practice prior to bid submission, CMS shared our intent to communicate application of the regulation for future years, such as through HPMS memoranda, as appropriate. We solicited comment on our various cost sharing limit proposals.

5. Comments Received and Responses for All Cost Sharing Provisions

We received feedback from 17 commenters on our proposal for codifying the methodology for setting certain cost sharing standards each year. The majority of comments were from health plans, provider associations, beneficiary and other advocacy organizations, and

pharmaceutical companies. A summary of the comments (generally by issue) and our responses follows:

Comment: Several commenters generally supported proposals to codify long-standing policies and increase transparency, including the methodology CMS uses to determine cost sharing limits described in section VI.B. of the February 2020 proposed rule. A commenter supported transitioning from subregulatory guidance to rulemaking and believed that the standardization, transparency, and predictability of formal rulemaking makes it a more appropriate vehicle for most provisions that make significant changes to the Medicare program. Another commenter appreciated the opportunity to provide feedback to guide implementation processes.

Response: We thank commenters for their support and feedback. CMS's goals for this proposal, in combination with section II.A. of this FC, include addressing potential stakeholder concerns about the impact of the MA eligibility changes for Medicare beneficiaries with diagnoses of ESRD on the methodology used for cost sharing limits and providing MA organizations with cost sharing flexibilities as an incentive to encourage favorable benefit designs for beneficiaries. Our aim is to provide transparency and predictability in how CMS calculates cost sharing thresholds for MA plans and evaluates MA organization compliance with cost sharing standards. We also intend this FC to encourage and facilitate stability in plan benefit design for beneficiaries. Proposing and codifying these flexibilities in regulation in advance of the years to which they will apply will encourage MA organizations to develop plan designs to take advantage of the flexibilities, as well as provide a measure of transparency and stability for the MA program. In addition, based on this rulemaking, MA organizations should have greater knowledge about how MA cost sharing limits are calculated and an ability to anticipate cost sharing limits in future years.

Consistent with our long-standing policy, most of the cost sharing standards we proposed and are finalizing apply only to in-network Parts A and B services and exceptions to that (where

limits will apply to out-of-network benefits) are explicitly stated. In-network service category cost sharing standards are inclusive of applicable service category deductibles, copayments and coinsurance, but do not include plan-level deductibles (for example, deductibles that include several service categories). In addition, as finalized, CMS will use Medicare FFS data projections (the definition is codified in § 422.100(f)(4)(i) as discussed in section II.A. of this FC) to calculate cost sharing limits for service categories subject to § 422.100(f)(6) and (j)(1); this is explicitly addressed in § 422.100(f)(7)(ii) and discussed in more detail in section II.B.5.a. of this FC. This means that unless otherwise stated, CMS will use projections of beneficiary outof-pocket costs for the applicable contract year, based on recent Medicare FFS data (including data for beneficiaries with and without diagnoses of ESRD) that are consistent with generally accepted actuarial principles and practices as outlined in paragraph (f)(7)(i) to calculate cost sharing limits. As a result, the Medicare FFS data projections used in calculating MA MOOP and cost sharing limits will encompass all original Medicare requirements, such as coverage restrictions and cost sharing limits. For emergency services (service category clarified as discussed in section II.B.5.e. of this FC.) and urgently needed services, the cost sharing limit applies whether the services are received inside or outside the MA organization's contracted network of providers and facilities (§ 422.113(b)(2)(i)), which is consistent with current policy and the obligation on all MA plans to cover such services both in-network and out-of-network without imposing any prior authorization limits. These considerations are generally aligned with our proposal to use the most recent Medicare FFS data projections to calculate MOOP and cost sharing limits and our longstanding practice of applying original Medicare rules to ensure MA plans are using cost sharing that is overall at least actuarially equivalent to Medicare FFS. In addition, this FC maintains the ability for D-SNPs to establish zero cost sharing for enrollees who are dually enrolled in both Medicare and Medicaid. For example, in a Zero-Dollar Cost Sharing D-SNP, Medicare inpatient hospital stays and doctor visits are available at no cost to the enrollee. A Medicare Non-Zero Dollar Cost Sharing D-SNP is a D-SNP under which the cost

sharing for Medicare Part A and B services varies depending on the enrollee's category of Medicaid eligibility.

The changes to the proposals we are finalizing in this FC range from minor edits, reorganizations, corrections, and clarifications to substantive modifications based on the comments received, operational considerations, and additional implementation of antidiscriminatory requirements (such as, to support equitable access to plans for beneficiaries with high health needs). Due to operational considerations and to help ensure that MA organizations have sufficient implementation time, the provisions in this FC will not be applicable until January 1, 2023. This reflects a one-year delay from the proposed implementation schedule. When MA bids for contract year 2023 are submitted for review and approval by the statutory deadline (June 6, 2022, for contract year 2023), the regulations in this FC will be used to evaluate those bids for approval. This change means that the dates in the proposed regulation text in §§ 422.100(f)(6), 422.100(j), and 422.113 have been updated from the February 2020 proposed rule (for example, changing a reference from January 1, 2022 to January 1, 2023) and we do not discuss those edits in much detail in our responses to comments and description of the final regulations. Changes to the implementation of the proposed policies that are more nuanced are explained (for example, section II.B.5.c. of this FC addresses the multi-year transition schedule of ESRD costs into inpatient hospital cost sharing limits). Further, we are adding descriptive headings to paragraphs (f)(6) introductory text and (f)(6)(i) through (iv) to identify the scope of the content in each paragraph. Additional changes to paragraphs (f)(6) introductory text and (f)(6)(i) through (iv) are discussed in sections II.B.5.a., b., and c. of this FC. Similarly, in our reorganization of proposed (i)(1) discussed in section II.B.5.e. of this FC, we are adding descriptive headings to paragraphs (j)(1)(i) and (ii). These headings are not substantive changes.

As discussed in section II.A. of this FC, the MOOP limits and cost sharing standards for contract year 2024 and future years will be communicated annually through a subregulatory

process, which we are finalizing at § 422.100(f)(7)(iii). This FC adopts the MOOP limits and specific cost sharing limits for contract year 2023 by applying the rules being finalized. As finalized in § 422.100(f)(7)(iii), beginning with contract year 2024, CMS will issue annual subregulatory guidance that specifies the MOOP limits and cost sharing standards that are set and calculated using the rules adopted in this FC; that guidance will be released prior to bid submission to allow sufficient time for MA organizations to prepare and submit plan bids. We expect this date will typically be by the first Monday in April. In addition, CMS will provide a public notice and comment period on the projected MOOP limits and cost sharing standards for the upcoming contract year unless a public comment period is impracticable, unnecessary, or contrary to the public interest. We believe these situations will be rare and intend to solicit comment annually, but believe that aligning the availability of prior notice and an opportunity to comment with rulemaking standards, which include authority to waive prior notice and a comment period when it is impracticable, unnecessary, or contrary to the public interest, is appropriate. For example, CMS may solicit and consider public comment on actuarial approaches before releasing the final MOOP limits and cost sharing standards. The exercise of actuarial judgment by the OACT may be a topic on which the public, or MA organizations, wish to comment when reviewing how CMS has applied the regulations adopted in this FC to calculate the benefit parameters for MA plans. As appropriate, we will consider such comments and may revise the decisions made in developing the projections and calculations of the MOOP and other cost sharing limits. To set the final contract year 2023 cost sharing limits following the methodology in this FC, CMS is using contract year 2023 Medicare FFS data projections (based on 2017 – 2021 Medicare FFS data) which reflect the OACT's actuarial judgements of expected costs in contract year 2023, including considerations of the impact from COVID-19. We did not codify the first Monday in April as a deadline to release the final MOOP limit and cost sharing standards or a specific minimum time frame for the comment period so CMS can remain flexible to potential future situations. The regulation provides for the release of subregulatory guidance

that addresses MOOP limits and cost sharing standards in advance of the upcoming plan year with sufficient time for MA organizations to prepare bids. For contract year 2023, we are releasing the final MOOP and cost sharing limits in this FC, in Tables 5 and 28. In addition, the final cost sharing limits for contract year 2023 through 2026 and future years for emergency services are provided in Table 24. Descriptions of the calculations CMS completed to reach these final contract year 2023 MOOP and cost sharing limits following the regulations finalized in this FC are available in section II.A.4. and II.B.5. of this FC.

February 2020 Proposed Rule Comment Solicitation for Bundled Copayments:

In the February 2020 Proposed Rule, CMS solicited comment on whether to codify the current guidance regarding bundled copayments. Our current guidance³² requires MA organizations to disclose and charge a single, bundled copayment in order to ensure that enrollees are provided accurate information about their potential financial liability (prior to and following enrollment in a plan) and to avoid confusion. Specifically, in situations where a facility or setting charges a separate amount from the health care provider that actually furnishes covered services, such as an emergency department fee and a fee for the emergency room physician, our guidance has been that those fees be combined (bundled) into the cost sharing amount for that particular place of service and be clearly reflected as a total copayment in appropriate materials distributed to beneficiaries. This longstanding guidance reflects CMS's interpretation of § 422.111 that enrollees be provided clear information about benefits and cost sharing that is not confusing. CMS received no comments regarding whether to codify this guidance.

CMS strives to make sure that plan cost sharing is transparent to MA enrollees and Medicare beneficiaries who are considering enrolling in MA. To ensure the MA regulations are sufficiently clear on these points, we are finalizing additional regulation text, at § 422.100(f)(9),

³² As referenced in Chapter 4, section 50.1 and the CY 2017 Final Call Letter; both documents may be accessed in the HHS Guidance Repository at: https://www.hhs.gov/guidance/.

to require that cost sharing (copayments and coinsurance) reflect the enrollee's entire cost sharing responsibility, inclusive of professional, facility, or provider setting charges, by combining (or bundling) all applicable fees into the cost sharing amount for that particular service(s) and setting(s) and be clearly reflected as a single, total cost sharing amount in appropriate materials distributed to beneficiaries. MA enrollees must receive the plan's Evidence of Coverage (EOC) document and other applicable plan materials that clearly disclose their total cost sharing responsibility for particular benefits. By requiring MA plans to clearly disclose and apply cost sharing this way, this FC will ensure that beneficiaries receive information about their financial responsibility for covered benefits through an MA plan and when comparing MA plans. We are finalizing this provision at § 422.100(f)(9) instead of in § 422.111 because it is about cost sharing and related to the cost sharing rules we are codifying in paragraph (f) even if the underlying purpose of the existing guidance and adequate information is provided to beneficiaries. Finally, this requirement about bundling cost sharing into one copayment amount applies to cost sharing for basic benefits.

a. General Non-Discriminatory Cost Sharing Limits (§ 422.100(f)(6))

Comment: CMS received mixed comments on the proposal to codify the long-standing policy, used in CMS's review of bids, that payment of less than 50 percent of the total MA plan financial liability discriminates against enrollees who need those services at § 422.100(f)(6)(i). A few commenters opposed CMS's proposal to allow MA plans with lower MOOP limits to establish cost sharing up to a 50 percent coinsurance, based on beneficiary discrimination concerns, and suggested that lower cost sharing would better protect beneficiaries who need higher-cost services. These beneficiary concerns were shared by other commenters generally or in relation to other specific cost sharing proposals and are also addressed, more comprehensively, in section II.B.5.b. of this FC.

A few commenters were generally supportive and requested clarifications or technical modifications. For example, a commenter requested CMS confirm that it did not intend to

require MA plans to measure financial liability at the individual item or service level or use the average allowable amount when calculating the copayment applicable to a specific transaction; the commenter noted that measuring financial liability at the "individual item or service level" would make the use of copayments very difficult, and would not correspond with other parts of the February 2020 proposed rule that indicated copayments are preferred over coinsurance. In addition, the commenter noted that MA plans may not have the average Medicare FFS allowed amount for each claim (which was referred to in the February 2020 proposed rule), but would have the plan's allowable amount for each particular provider to calculate a cost sharing threshold. Similarly, another commenter requested CMS allow the average contracted rate to be calculated at the parent organization level for purposes of determining compliance with the 50 percent total MA plan financial liability limit. This commenter noted that this approach would allow MA organizations the ability to consider credibility when setting cost sharing limits to help create year over year cost sharing stability for beneficiaries. CMS believes the commenter was referencing claims credibility for pricing purposes in their comment.

Response: We appreciate the support and questions from commenters seeking guidance on how to implement and demonstrate compliance with our proposal to codify the longstanding policy for out-of-network basic benefits and in-network basic benefits that are in service categories for which CMS has not otherwise established a cost sharing standard. The requirement that MA organizations must pay at least 50 percent of the total MA plan financial liability for the benefit protects beneficiaries with high health needs and ensures an equitable plan design that balances overall costs between the MA plan and enrollees. In addition to addressing these concerns, we take this opportunity to explain the changes we are finalizing to § 422.100(f)(6), (f)(6)(i), and new paragraph (f)(7) that are related to the overall policies being adopted for calculating MA cost sharing limits. In brief, paragraph (f)(7) codifies how CMS will utilize generally accepted actuarial principles and practices, Medicare FFS payment data,

Medicare FFS and MA utilization data, and other factors as part of calculating the copayment

limits for the cost sharing standards in this FC. We explain how these clarifications, modifications and new paragraphs apply to service categories subject to paragraph (f)(6)(i), as well as cost sharing limits set under other paragraphs. The method by which an MA organization identifies estimated total MA plan financial liability for purposes of ensuring that its cost sharing does not exceed 50 percent of that amount is similar to the process an MA organization would use to ensure that MA cost sharing complies with the other limits we proposed and are finalizing in § 422.100(f)(6). We believe addressing these changes first in this response will provide context and clarity regarding how MA organizations may implement and demonstrate compliance with the rules finalized in § 422.100(f)(6)(ii), (f)(6)(iii), and (j)(1). The specific cost sharing standards finalized at § 422.100(f)(6)(iii) and (j)(1) are explained in more detail in section II.B.5.b and II.B.5.e. of this FC.

MA organizations previously and currently have flexibility to establish cost sharing up to 50 percent coinsurance for many benefits, but generally do not establish cost sharing amounts at the maximum allowable cost sharing limit for most service categories. MA organizations typically offer benefits with lower cost sharing amounts than the permitted maximum cost sharing limits for the vast majority of service categories (such as primary care physician). While we do not have definitive data, we believe this is due to multiple factors, including the principles and incentives inherent in managed care, effective negotiations between MA organizations and providers, and market competition. Further, the requirement that cost sharing for basic benefits overall must be actuarially equivalent to cost sharing in original Medicare, with the ability to reduce cost sharing as a supplemental benefit, discourages MA plans from using extremely high cost sharing. In addition, we expect beneficiary preferences will continue to act as an incentive for MA organizations to offer favorable benefit designs. Also, several professional service category cost sharing standards calculated in this FC for intermediate and mandatory MOOP types (as discussed in section II.B.5.b. of this FC) are lower than what would be allowable under CMS's longstanding policy that cost sharing not exceed 50 percent of the estimated total MA

plan financial liability for the benefit. Considering these factors, CMS expects that codifying this longstanding policy will not result in significant increases in cost sharing amounts for enrollees compared to prior contract years as MA organizations have incentive to maintain a competitive position in the market.

Our rule explicitly addresses both copayment and coinsurance structures. We proposed (at § 422.100(f)(6)(i)(A), (B), and (C)) that coinsurance cannot exceed 50 percent of the total MA plan financial liability and specific rules for setting copayments based on that percentage limit. We are finalizing similar, but not identical requirements, at paragraph (f)(6)(i) to consolidate and simplify the regulation. We did not intend by our proposal at paragraph (f)(6)(i) that copayments would be required to vary with each specific encounter (that is, that the copayment amount for a particular item or service would vary based on the payment rate to a specific provider for that service). To ensure clarity in the regulations on this point, we are finalizing the introductory language in paragraph (f)(6) with a revision to explicitly provide that cost sharing may be a coinsurance or copayment for a plan benefit package service category or for a reasonable group of benefits covered under the plan. This means that copayments are not required to vary by specific provider, item, or service, based on the provider's payment amount but rather must be set at a dollar amount that applies to visits of the identified service category of benefits. This reflects CMS's intent to codify the less burdensome, longstanding policies that are familiar to MA stakeholders. In tandem with this modification to paragraph (f)(6), we are not finalizing the proposed regulation text in paragraph (f)(6)(i)(C) about using the MA organization's average contracted rate of that benefit (item or service) to calculate the copayment dollar amount for out-of-network benefits. Rather, we are finalizing rules in paragraph (f)(6)(i) to require that MA plans must not establish a cost sharing amount that exceeds 50 percent coinsurance or an actuarially equivalent copayment value for the service category or for a reasonable group of benefits in the PBP. This includes finalizing rules for the data used by the MA organization to determine an amount that is actuarially equivalent to 50 percent coinsurance,

including authority to use the average Medicare FFS allowable amount (as proposed in paragraph (f)(6)(i)(C)). CMS will monitor copayment amounts and coinsurance percentages as part of our annual bid review process during which we examine plan cost sharing. In addition, MA organizations may use the estimated total MA plan financial liability for the service category or for a reasonable group of benefits in the PBP for that contract year to determine the actuarially equivalent value to 50 percent coinsurance. With this approach, we intend to permit the MA organization to use aggregate payment data about the service category, or for the reasonable group of benefits, to which the cost sharing applies when determining the dollar figure that is actuarially equivalent to 50 percent coinsurance. That dollar figure would be the maximum permissible copayment amount for the service category or group of benefits. In addition, we are adopting a provision that an MA plan must not charge an enrollee a copayment for a basic benefit that is greater than the cost of the covered service(s). We believe that this important enrollee protection is necessary and a corollary of our proposal that MA plans be responsible for at least 50 percent of total MA plan liability for basic benefits, whether furnished in-network or out-of-network. As this FC clarifies that our cost sharing limits apply at the service category level (or a reasonable group of benefits), we are finalizing regulation text to explicitly protect enrollees from paying more cost sharing than the estimated total MA plan financial liability for the covered service(s).

When CMS evaluates compliance, either through reviewing bids or other oversight activities, it may not examine in detail a plan's compliance with cost sharing standards for every service category. Also, CMS might not calculate and publish actuarially equivalent copayment values for every service category or situation. Nevertheless, the regulations we are finalizing here will continue to apply to all MA cost sharing charged for basic benefits. Sections II.B.5.b. through II.B.5.f. of this FC finalize specific cost sharing requirements for some in-network benefits in addition to the rule in paragraph (f)(6)(i) for all other in-network and out-of-network benefits (for example, certain categories of benefits in § 422.100(f)(6)(iii) and (iv) and specific

services and categories in § 422.100(j)(1)). Section II.B.5.d. of this FC also finalizes specific cost sharing limits for emergency and urgently needed services in § 422.113(b)(2). MA plans (at the segment-level, if applicable) must comply with all of these requirements. To ensure clarity on this point, the introductory text in paragraph (f)(6) requires that an MA organization must establish cost sharing for basic benefits that complies with the standards in §§ 422.100(f)(6) and (i) and 422.113(b)(2) and codifies longstanding policy of how CMS completes cost sharing evaluations at the plan (or segment) level. These standards include coinsurance and specific copayment limits specified in the regulations or copayment limits calculated by CMS using the methodology identified in those regulations. As proposed and finalized with clarifying edits and additions, § 422.100(f)(6) states that these requirements are in addition to other limits and rules applicable to MA cost sharing, such as the requirement that the overall MA cost sharing for basic benefits be actuarially equivalent to Medicare FFS cost sharing (that is, the PMPM actuarial equivalence evaluation in § 422.254(b)(4) and as finalized in paragraph (j)(2)). In situations where CMS does not calculate a copayment limit for a particular service category specified in these regulations, then the copayment amount that the MA organization sets for that service must not exceed the actuarially equivalent value limit of the applicable coinsurance for the MOOP limit of the plan. Consistent with this, we are generally maintaining the current language in paragraph (f)(6) regarding how cost sharing for basic benefits specified by CMS must not exceed levels annually determined by CMS to be discriminatory for such services. This is consistent with how, currently, MA organizations establish copayment amounts that do not exceed maximum coinsurance limits in those instances where CMS does not calculate a specific copayment limit. We are also finalizing rules for the data to be used in calculating the actuarially equivalent values that would be used in CMS's calculation of copayment limits and evaluation of MA plan copayments.

We are finalizing at § 422.100(f)(6)(i) with a rule prohibiting MA plans from paying less than 50 percent of the estimated total MA plan financial liability for that contract year or the

average Medicare FFS allowable amount for the plan service area for the benefit, which is generally what we proposed in paragraph (f)(6)(i)(A) with additions for clarity that remain consistent with our longstanding policy. For example, as discussed in more detail subsequently in this response, the addition of "estimated" to the term "total MA plan financial liability" in paragraph (f)(6)(i) recognizes that MA organizations may not have the data necessary to determine the final total MA plan financial liability for the benefit sufficiently in advance of the bid submission deadline. In addition, instead of stating the rule as how much an MA plan must pay, we are finalizing the rule as a limit on the cost sharing that an MA plan may impose on enrollees. As proposed, this rule regarding the 50 percent limit on cost sharing applies to all outof-network basic benefits. While the proposed paragraph (f)(6)(i)(A) referred to paragraph (f)(6)(i), this FC clarifies that the 50 percent coinsurance limit applies to service categories that are not subject to other specific cost sharing standards set under §§ 422.100(f)(6) and (j)(1) and 422.113(b)(2). While we proposed (and are finalizing in sections II.B.5.b. through II.B.5.e. of this FC.) separate cost sharing standards and requirements for professional services, inpatient hospital service categories, emergency services, and a prohibition on cost sharing for certain specific benefits that exceeds the cost sharing under original Medicare, we believe that additional clarity on this point improves the regulation.

Setting limits on cost sharing for covered services and ensuring MA organizations comply with these limits are important ways to ensure that the cost sharing aspect of a plan design does not discriminate against or discourage enrollment in an MA plan by beneficiaries who have high health care needs. CMS has historically evaluated bid and market data to identify areas of concern and conduct research, and has added new service category cost sharing limits based on these analyses. For example, prior to contract year 2017, CMS did not set a copayment limit for cardiac rehabilitation. In the CY 2017 Call Letter³³, we noted that cardiac rehabilitation

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³³ Call Letters communicating CMS policy for contract years prior to 2021 may be accessed here: https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents.

(a professional service that will be subject to the cost sharing limits in § 422.100(f)(6)(iii)) was an area of concern and, as part of reviewing bids for contract year 2017 through 2019, we asked MA organizations to justify cost sharing above \$50 for cardiac rehabilitation services. Then, for contract year 2020 we added specific cost sharing standards for cardiac rehabilitation services that MA plans could not exceed. As a result, the services for which we announce cost sharing limits and how CMS evaluates an MA plan's cost sharing have operationally varied in past years to be responsive to changes to market conditions and Medicare FFS payment policy. We intend to continue this approach to how CMS expends its resources in calculating copayment values under this FC, in general oversight activities, and in evaluating bid submissions. For example, we have not previously set a specific copayment limit for each specific category of DME but since the February 2020 proposed rule we have reviewed contract year 2023 Medicare FFS data projections (based on 2017 – 2021 Medicare FFS data) to calculate a contract year 2023 copayment limit for the "DME – shoes or inserts" and "DME – diabetes monitoring supplies" service categories for MA plans that establish a lower or intermediate MOOP limit. This copayment limit is actuarially equivalent to the longstanding 50 percent coinsurance limit, which will continue to apply to these categories per $\S 422.100(f)(6)(i)$. The calculations of the final contract year 2023 copayment limits for those DME service categories using the rules in paragraph (f)(6)(i) are included subsequently in this response. In addition, the complete list of final contract year 2023 cost sharing limits for in-network services are summarized in Table 28. While not applicable for contract year 2023, we are evaluating Medicare FFS data projections and considering future copayment limits for other categories that are subject to paragraph (f)(6)(i) that are not included in Table 28, such as ambulance services. If we determine that it is appropriate to apply the rules in § 422.100(f)(6)(i) to calculate a copayment value that is actuarially equivalent to the mandatory 50 percent coinsurance limit, we may announce that copayment limit using the guidance issued under § 422.100(f)(7)(iii) for contract year 2024 or another future year.

As MA organizations may continue to establish coinsurance up to 50 percent, we do not believe that CMS retaining flexibility to calculate a copayment limit that equates to that coinsurance level reflects a change from current practice. Nor does the manner by which CMS calculates the copayment limits under this FC represent a drastic change. When CMS calculates an actuarially equivalent copayment limit for a service category subject to § 422.100(f)(6)(i), the administrative burden for MA plans may be reduced. In the past, when CMS did not set a copayment limit, MA organizations that use copayments instead of coinsurance generally had to submit supporting documentation to show how the MA plan's copayment met the 50 percent coinsurance standard. While, going forward, we may not require documentation demonstrating the calculation of every copayment used by an MA plan, documentation or justifications may be necessary in some cases to demonstrate compliance with the regulation. For service categories where we calculate a copayment that is actuarially equivalent to 50 percent coinsurance (such as "DME – diabetic shoes or inserts" as shown in Table 28), MA organizations will not need to provide supporting documentation if the MA plan's copayments are below the values calculated and issued by CMS under § 422.100(f)(6).

We are including information in Table 28 to illustrate how the 50 percent cap on cost sharing for basic benefits that are not addressed by other regulations will interact with the other regulations specifying cost sharing limits. Table 28 identifies 50 percent coinsurance as the cost sharing limit for all the DME service categories for MA plans that establish a lower or intermediate MOOP limit. This is a clarifying update from the "N/A" designations for the same service categories and types of MOOP limits in the February 2020 proposed rule's Table 5 (Illustrative Contract Year 2022 In-Network Service Category Cost Sharing Limits) and from subregulatory guidance in prior contract years for MA plans that established a voluntary MOOP limit.³⁴ Other services not included on the chart continue to be subject to paragraph §

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³⁴ See Table 5: CY 2021 In-Network Service Category Cost Sharing Requirements from the HPMS memorandum titled "Final Contract Year 2021 Part C Benefits Review and Evaluation," issued April 8, 2020.

422.100(f)(6)(i), such as ambulance services (50 percent coinsurance limit regardless of MOOP type). We believe these clarifications will increase understanding and transparency in how § 422.100(f)(6)(i) applies.

As finalized, § 422.100(f)(6)(i) imposes limits on the cost sharing that may be charged to enrollees for out-of-network and in-network basic benefits for which another regulation has not otherwise calculated a cost sharing standard. This rule provides flexibility for CMS to calculate the value for copayment limits for new categories of basic benefits when CMS determines it is appropriate. This flexibility and how we intend to use it are consistent with CMS's prior practice for calculating copayment limits. For benefits subject to § 422.100(f)(6)(i), the enrollee coinsurance cannot exceed 50 percent and the copayment must be no greater than an actuarially equivalent value for that coinsurance regardless of the type of MOOP limit established by the plan (with one exception for the DME service categories for the mandatory MOOP limit, as discussed in section II.B.5.e. of this FC). Similarly, as proposed at § 422.100(f)(6)(iii)(C) (finalized with clarifying additions at § 422.100(f)(6)(iii)(C) – (F)), an MA plan must pay at least a specified percentage of the estimated total MA plan financial liability for the covered benefit for that contract year. As discussed in a subsequent response to comment in this section, the cost sharing limits imposed by §422.100(f)(6)(i), like other cost sharing limits finalized in this FC, are also subject to the rounding rules finalized in paragraph (f)(6)(ii).

As also discussed in section II.A. of this FC, calculation of the MOOP and cost sharing limits using the methodologies and standards finalized in §§ 422.100(f) and (j) and 422.101(d) requires the exercise of actuarial judgment and the use of generally accepted actuarial principles and practices. Our proposal in the February 2020 proposed rule implicitly acknowledged the use of these principles and practices as a longstanding part of how CMS calculates cost sharing limits and it is inherent in how the OACT performs many of the projections and calculations. Specifically, the February 2020 proposed rule discussed how the OACT conducted necessary analyses and projections in the past and made clear that the OACT would be involved in

applying the methodologies to calculate the MOOP and cost sharing limits we were proposing. As a result, while not explicitly proposed, CMS is finalizing a new regulation at § 422.100(f)(7)(i) that addresses use of generally accepted actuarial principles and practices by CMS and MA organizations to ensure that this FC provides more detail regarding the actuarial nature of how costs are projected (which we believe is better stated in the regulation text). This new provision describes how generally accepted actuarial principles and practices will be used in: (1) developing the beneficiary cost sharing projections used to calculate the MOOP limits in § 422.100(f)(4) and (f)(5) and § 422.101(d)(2) and (d)(3) and the inpatient hospital acute and psychiatric service category cost sharing limits in § 422.100(f)(6)(iv); (2) calculating the copayment values that are actuarially equivalent to the coinsurance limits set for service categories in § 422.100(f)(6)(i), for professional services in § 422.100(f)(6)(iii), and for the benefits for which MA cost sharing may not exceed cost sharing under original Medicare in § 422.100(j)(1); (3) evaluating MA organization compliance with §§ 422.100(f)(6) and (j); and (4) developing the projections and calculations used in applying § 422.100(f)(8) for transitioning current (contract year 2022) copayment limits to the copayment limits produced by the methodology adopted in § 422.100(f)(6)(iii), (f)(7)(ii), and (j)(1), as discussed in more detail in section II.B.5.b. and e. of this FC. Under § 422.100(f)(7)(i), CMS and MA organizations must use generally accepted actuarial principles and practices for these purposes. As a result, in paragraph (f)(6)(i) we refer to paragraph (f)(7) as applying when CMS calculates copayment limits that are at an actuarially equivalent value to 50 percent coinsurance for service categories representing in-network basic benefits that are not otherwise addressed in paragraph (f)(6), (j)(1), or in § 422.113(b)(2).

CMS's longstanding practice in developing and setting MOOP and cost sharing limits has been to use generally accepted actuarial principles and practices in developing the projections of beneficiary costs. In projecting out-of-pocket costs and utilization based on the Medicare FFS data projections (as defined in § 422.100(f)(4)(i)) for CMS to use in calculating MOOP and cost

sharing limits for contract year 2023 and future years, the OACT will continue to use generally accepted actuarial principles and practices. In the past, we have considered all or some of the following information when setting copayment limits: (1) projected median or average total Medicare FFS allowed amounts (occasionally weighted by utilization, including place of service and/or provider type, as applicable); and (2) a Medicare FFS claims cost distribution. In continuing this practice under the rules adopted in paragraph (f)(7)(i)(A) when calculating cost sharing limits, we may take into account the number of visits or sessions a beneficiary typically receives in order to reach an actuarially equivalent copayment amount for a service category that is subject to a wide-range of costs. For example, as discussed in the February 2020 proposed rule, we calculated the illustrative copayment limit for the "mental health specialty services" service category in Table 5 (Illustrative Contract Year 2022 In-Network Service Category Cost Sharing Limits) from the February 2020 proposed rule by weighting the average Medicare FFS allowed amount by the utilization of specific relevant provider specialty types (clinical psychologist, licensed clinical social worker, and psychiatry). As discussed in section II.B.5.b., the contract year 2023 actuarially equivalent copayment value for the "mental health specialty services" service category is calculated by weighting the average Medicare FFS allowed amount by the utilization of the same provider specialty types using updated Medicare FFS data projections. We will also consider the purpose of the cost sharing limits and their role in the MA program when deciding among different approaches and, if it is appropriate, to take additional data into consideration in making projections and calculating cost sharing and MOOP limits using generally accepted actuarial principles and practices. As codified in paragraph (f)(7)(i)(A), information such as changes in legislation (such as, changes in Medicare benefits), Medicare payment policy, trends over several years of data, and external variables (such as public health emergencies) may be taken into account when performing the calculations and projections used to set the MOOP limits and cost sharing limits. The OACT considers these variables as they develop their projections by applying trend factors (that are consistent with the most recent

Medicare Trustees Report). In addition, future impacts of laws and regulations are factored into OACT's projections. Specifically, actuaries use their professional judgment when selecting methods and assumptions, conducting an analysis, and reaching a conclusion which is consistent with generally accepted actuarial standards and principles. ³⁵ For example, the OACT is applying trend factors that reflect the expected volatility and impact of COVID-19 on the Medicare FFS utilization data from prior years in order to determine the Medicare FFS data projections for 2023 and subsequent years that CMS will use to calculate the MOOP and cost sharing limits for those future years. This is an example of how external variables may be taken into account. Actuarial judgment will be exercised in other matters as appropriate in applying the regulatory standards. When MA organizations use and apply generally accepted actuarial principles and practices to calculate actuarially equivalent copayment values when required under this FC, we anticipate that, MA organizations will take similar considerations into account. In addition, paragraph (f)(7)(i)(B) codifies that MA organizations must also use generally accepted actuarial principles and practices in complying with the regulations in paragraphs (f)(6) and (j) of this section. Finally, paragraph (f)(7)(i)(C) requires the same principles and practices to be used by CMS in evaluating MA plan compliance with paragraphs (f)(6) and (j). In summary, the approach allowing for actuarial professional judgments in making the projections and calculations used in applying the methodologies to set and comply with the cost sharing limits from this FC is adopted in paragraph (f)(7)(i), to clarify our intent and to be consistent with prior practice.

In addition to complying with § 422.100(f)(7)(i), we will follow the same process and apply the same considerations in calculating the values needed for copayment limits that are actuarially equivalent to the coinsurance percentages specified in the regulation text in § 422.100(f)(6)(i), (f)(6)(iii), and (j)(1). Rather than repeat those standards in each regulation, we

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³⁵ See Actuarial Standards Board, Actuarial Standard of Practice No. 1, adopted March 2013, Sections 2.9 and 3.1.4 https://www.actuarialstandardsboard.org/wp-content/uploads/2013/10/asop001_170.pdf) and http://www.actuarialstandardsboard.org/profcounts/asop-no-1-and-professional-judgment/.

are codifying them in a new provision at § 422.100(f)(7)(ii). As discussed previously, CMS may not calculate a specific copayment limit for every service category; if we do, it will be in compliance with paragraph (f)(7). New paragraph (f)(7)(ii) provides that CMS calculates copayment limits as feasible and appropriate to carry out program purposes and paragraphs (f)(7)(ii)(A) through (E) outline the process and standards for that. Paragraphs (f)(7)(ii)(A) and (B) address the data CMS will use in calculating copayment limits. As referenced in the February 2020 proposed rule, CMS has annually analyzed Medicare program data to set the various cost sharing limits under current law and to publish guidance on MA cost sharing limits. The relevant Medicare data has included the most recent Medicare FFS data, including cost and utilization data and, in some cases, MA patient utilization information from MA encounter data. For example, CMS has used patient utilization from MA encounter data to inform inpatient hospital acute and psychiatric length of stay scenarios used in identifying MA plan cost sharing standards that are not discriminatory. Paragraph (f)(7)(ii)(A) codifies how CMS will use Medicare FFS data projections (as defined in paragraph (f)(4)(i)) for the applicable year and service category in order to calculate copayment limits for service categories subject to paragraph (f)(6)(i), (iii), and (j)(1). Development of the Medicare FFS data projections are based on Medicare FFS cost and utilization data for specific services and service categories. If available and where appropriate to consider utilization differences between Medicare FFS beneficiaries and MA enrollees to reach a value that most closely reflects an actuarially equivalent copayment for the benefit and beneficiary population, paragraph (f)(7)(ii)(B) codifies how CMS may also use patient utilization information from MA encounter data in our calculations. For example, if the utilization of different settings of service (such as, outpatient hospital compared to physician office) were available, comparable, and significantly different between Medicare FFS and MA encounter data, we may weight Medicare FFS cost data projections by MA encounter utilization of the relevant facility and provider types in order to calculate a cost sharing limit that is most closely actuarially equivalent to what MA enrollees

may typically experience. In many cases, we may determine that MA encounter data is sufficiently available and recent for the relevant service category in order to apply analyses of MA utilization encounter data in our copayment limit calculations. CMS will complete accuracy checks in determining whether and when to use MA encounter data when paragraphs (f)(6)(iv) and (f)(7)(ii) permit use of that data. (See section II.B.5.c. of this FC for discussion of § 422.100(f)(6)(iv).) As a result, we clarify here that the use of MA encounter data is not mandatory under paragraph (f)(7)(ii)(B) for calculating cost sharing limits. Rather, use of MA encounter data may be informative for CMS and the OACT to consider in making decisions about the actuarial approach to apply to the Medicare FFS data projections.

Consistent with prior practice and as finalized in new § 422.100(f)(7)(ii)(C), CMS will be guided by what is appropriate to carry out program purposes when deciding how to calculate copayment limits for a service category identified in these regulations using the data described in paragraphs (f)(7)(ii)(A) and (B). Program purposes include such considerations as setting copayment limits that most closely reflect an actuarially equivalent copayment for the benefit and beneficiary population, protecting against discriminatory cost sharing, and avoiding unnecessary fluctuations in cost sharing that may confuse beneficiaries. These considerations will guide how judgement is exercised when generally accepted actuarial principles and practices provide choices and discretion. In situations where there are multiple or a range of actuarially equivalent copayment values for a service category, CMS will select a particular approach to calculate an actuarially equivalent copayment value in order to carry out those program purposes. For example, CMS may choose the methodology that results in the lowest possible increase or change in cost sharing for enrollees from the prior year, if there are multiple methodologies that are actuarially acceptable in calculating an actuarially equivalent copayment value. This approach is consistent with the stated goal in the February 2020 proposed rule to protect enrollees from increases in cost sharing when possible and including it in the regulation text provides additional transparency for stakeholders. In addition, in a situation where there are

multiple approaches resulting in multiple actuarially equivalent values, CMS may choose the actuarial approach that is most consistent with trends and patterns in MA utilization and costs, if such information is available. For example, in the February 2020 proposed rule we explained that CMS proposed to add new cost sharing limits for an inpatient hospital acute 3-day length of stay scenario because it represented the median length of stay based on separate analyses of Medicare FFS and MA encounter data (for the same time period). A similar comparison may be completed if MA encounter data is also available related to a service category subject to paragraph (f)(6)(i), (f)(6)(iii), or (j)(1). While helpful for comparison purposes and to inform which measure of central tendency CMS should use, MA encounter cost data will not be used to calculate the copayment limits. This approach further protects beneficiaries and plan designs from potentially disruptive changes to cost sharing.

As discussed in section II.B.5.b. and e. of this FC, we are finalizing at § 422.100(f)(8) a transition for copayment limits calculated under this FC. New paragraph (f)(7)(ii)(D) provides that actuarially equivalent copayment limits will be consistent with that transition. The actuarially equivalent copayment transition finalized at § 422.100(f)(8) is only applicable to service categories subject to paragraphs (f)(6)(iii) and (j)(1). Similarly, as discussed in section II.A. and II.B.5.c. of this FC, the transition of ESRD costs (finalized in paragraph (f)(4)(vi)) is only applicable for the methodology CMS uses to calculate MOOP and inpatient hospital cost sharing limits. Specifically, service categories subject to paragraph (f)(6)(i) are not subject to paragraph (f)(4)(vi) (the ESRD cost transition) or paragraph (f)(8) (the transition to actuarially equivalent copayments) because CMS has not historically calculated copayment limits in addition to the 50 percent coinsurance limit for most of these benefits in prior years. Finally, § 422.100(f)(7)(ii)(E) applies the rounding rules in paragraph (f)(6)(ii) as a necessary part of the copayment limit calculations. The rounding rules are discussed in more detail in a subsequent response to comment in this section.

In summary, § 422.100(f)(7)(i) and (ii) generally codify elements of our existing practice

and policy for cost sharing limits and clarifies how the necessary judgment will be used in developing actuarially sound projections of beneficiary out-of-pocket costs (to calculate MOOP limits) and actuarially equivalent copayment amounts. As in the past when calculating cost sharing limits, CMS will conduct analyses and make projections using the various data described in the regulation. Taken together, § 422.100(f)(6), (f)(6)(i), and (f)(7) require an MA plan use cost sharing that is no greater than 50 percent coinsurance or an actuarially equivalent copayment value, with that copayment value calculated and announced by CMS or, if CMS does not calculate a copayment limit, based on the average Medicare FFS allowable amount for the plan service area or the estimated total MA plan financial liability for that contract year, for innetwork benefits that are not otherwise addressed in §§ 422.100(f)(6), (j)(1), or 422.113(b)(2) and for out-of-network basic benefits.

To illustrate application of the methodology and how we intend to interpret and rely on § 422.100(f)(7)(i) and (ii) for a service category subject to paragraph (f)(6)(i), we explain here the development of final contract year 2023 copayment limits for the specific service category of "DME – diabetic shoes or inserts." The copayment limit must be actuarially equivalent to 50 percent coinsurance for MA plans that establish a lower or intermediate MOOP amount. (As discussed in section II.B.5.e. of this FC, MA plans that establish a mandatory MOOP amount must have cost sharing that does not exceed cost sharing in original Medicare (that is, 20 percent coinsurance) for the specific service categories of DME specified in § 422.100(j)(1)(i)(E).) We acknowledge that the February 2020 proposed rule stated that the "DME" service category was one of several categories identified as subject to a higher variation in cost or unique provider contracting arrangements, which makes Medicare FFS average or median cost data less suitable for developing a standardized actuarially equivalent copayment value. Since then, we have worked closely with the OACT to analyze additional and updated Medicare FFS data projections for these service categories. CMS has been able to make progress to address and apply actuarial approaches (consistent with finalized paragraphs (f)(7)(i) and (ii)) to address these concerns

(such as, weighting by the number of visits or sessions a beneficiary typically receives in order to reach an actuarially equivalent copayment amount for a service category that is subject to a wide range of costs). Table 10 includes the calculations of the actuarially equivalent copayment values for both the DME "diabetic shoes or inserts" and "diabetes monitoring supplies" service categories for the lower and intermediate MOOP types using contract year 2023 Medicare FFS data projections (based on 2017 – 2021 Medicare FFS data). Table 28 illustrates the results of applying paragraphs (f)(6), (f)(7), (f)(8), and (j)(1) to set final contract year 2023 in-network service category cost sharing limits. As a result, the actuarially equivalent copayment values from row D in Table 10 are included in Table 28 as the final contract year 2023 copayment limits for those DME service categories and MOOP types. The copayment values listed in Tables 10 and 28 for a lower and intermediate MOOP limit for the "DME – diabetic shoes or inserts" service category are the CMS-calculated actuarial equivalent value for a 50 percent coinsurance cost sharing limit. As illustrated in Table 10, to calculate this actuarially equivalent copayment value, we started with the contract year 2023 Medicare FFS data projections from the OACT. Based on HCPCS codes from the Medicare FFS data projections, the projected weighted average total Medicare FFS allowed amount for the "DME – diabetic shoes or inserts" service category equals \$47.51 for contract year 2023. CMS weighted this projected average Medicare FFS allowed amount by utilization of pairs of diabetic shoes, inserts, and shoe modifications. We chose to weight the relevant HCPCS codes (A5500, A5501, A5512, A5513, and A5500) by utilization as there was a relatively wide range of costs projected for 2023, approximately \$30 to \$220, depending on whether the item was a custom molded shoe, insert, or shoe modification. Weighting the projected average costs by utilization results in a value that more accurately represents an actuarially equivalent value to the costs the OACT projects will be experienced by Medicare FFS beneficiaries. Using 50 percent of the projected Medicare FFS weighted average amount (\$23.76), and applying the rounding rules in paragraph (f)(6)(ii), we reached \$25.00 as an actuarially equivalent copayment value to 50 percent coinsurance for this service category for

MA plans that establish a lower or intermediate MOOP amount in contract year 2023. CMS completed similar analyses to calculate and set a final contract year 2023 copayment limit that is actuarially equivalent to 50 percent coinsurance for the "DME – diabetes monitoring supplies" service category in Table 28.

As CMS did not set copayment limits for service categories subject to the longstanding 50 percent coinsurance limit in prior years, the limits we are adopting in paragraph (f)(8) to transition to actuarially equivalent values are not relevant for the DME service categories for MA plans that establish a lower or intermediate MOOP. Accordingly, Table 28 reflects a final contract year 2023 \$25 copayment limit for the "DME – diabetic shoes or inserts" service category and a \$20 copayment limit for the "DME – diabetes monitoring supplies" service category for MA plans with a lower or intermediate MOOP limit in addition to the 50 percent coinsurance limit. As discussed in section II.B.5.e. of this FC, the same starting figures (\$47.51 and \$39.48 for the DME "diabetic shoes or inserts" and "diabetes monitoring supplies" service categories, respectively) were used to calculate an actuarially equivalent copayment value to 20 percent coinsurance to reach the final contract year 2023 copayment limits for the mandatory MOOP type. Applicable MA encounter utilization data was not available at the time CMS was making these calculations, so all final contract year 2023 copayment limits in Table 28 are solely based on Medicare FFS costs and utilization (including for the DME service categories). In addition, based on the available Medicare FFS data projections, CMS (in consultation with the OACT) did not conclude that another approach would be better suited to calculate an actuarially equivalent copayment value for these DME service categories.

TABLE 10: CMS CALCULATIONS OF THE FINAL CONTRACT YEAR 2023 COPAYMENT LIMITS FOR THE DME "DIABETIC SHOES OR INSERTS" AND "DIABETES MONITORING SUPPLIES" SERVICE CATEGORIES SUBJECT TO § 422.100(f)(6)(i) FOR THE LOWER AND INTERMEDIATE MOOP TYPES USING CONTRACT YEAR 2023 MEDICARE FFS DATA PROJECTIONS (BASED ON 2017 – 2021 MEDICARE FFS DATA)

Row Reference	Description	DME – Diabetic Shoes or Inserts	DME – Diabetes Monitoring Supplies
A	Contract year 2023 Medicare FFS projections of total weighted average cost*	\$47.51	\$39.48
В	Contract year 2023 coinsurance limit per § 422.100(f)(6)(i)		50%
С	Unrounded actuarially equivalent copayment value to contract year 2023 coinsurance limit per § 422.100(f)(6)(i) (row A multiplied by row B)	\$23.76	\$19.74
D	Rounded actuarially equivalent copayment value to contract year 2023 coinsurance limit (row C rounded per § 422.100(f)(6)(ii))	\$25.00	\$20.00

^{*}The OACT employed generally accepted actuarial principles and practices in calculating these projected amounts (as finalized in § 422.100(f)(7)).

Consistent with § 422.100(f)(7), we may calculate actuarially equivalent copayment limits for the other DME service categories and other categories subject to § 422.100(f)(6)(i) (such as ambulance services) in future years (as those categories do not have final contract year 2023 copayment limits in Table 28) as feasible and appropriate to carry out program purposes. Considerations include whether additional Medicare FFS data projections are available and suitable (based on paragraph (f)(7)(i)), the need for CMS to prioritize use of its resources, and whether calculating a copayment limit would assist CMS in protecting against discriminatory cost sharing and avoiding unnecessary fluctuations in cost sharing that may confuse beneficiaries. These considerations and calculations of copayment limits will be completed annually based on the Medicare FFS data projections for the applicable year and service category. Conversely, there may be years where CMS does not exercise its authority to apply the methodology in these regulations to calculate a specific copayment limit for a particular basic benefit. In this case, if the MA organization wants to establish a copayment for a benefit where CMS has not calculated the actuarially equivalent copayment limit, the MA organization must apply these regulations to calculate the actuarially equivalent value of a particular coinsurance percentage for that basic benefit using the data specified in the regulations (for example, the MA plan's estimated total financial liability for that contract year). The reasons for CMS's approach

each year may vary, such as that CMS resources may be better devoted to other program responsibilities or available data projections are insufficient to produce an actuarially equivalent copayment value for that year. However, preliminary analyses could indicate that there is a copayment level which clearly does not exceed the limits set in this regulation for copayments. It might be beneficial for CMS to provide that information along with an indication that CMS does not believe that scrutiny is required of copayments established by an MA plan at or below that level. In those cases, as no copayment limit has been officially issued by CMS, MA plans would need to be able to validate how a copayment established above that copayment level complies with the regulatory standards.

Under this FC, MA organizations may choose a copayment or coinsurance form of cost sharing for any in-network or out-of-network benefit. If the plan chooses to establish a copayment, the amount is limited to an actuarially equivalent value based on the applicable regulation standard. When using copayments for benefits where CMS has not calculated the value that is actuarially equivalent to the maximum coinsurance percentage value, MA organizations must also use generally accepted actuarial principles and practices and the type of data that is described in paragraphs (f)(6)(i) and (iii). We are finalizing § 422.100(f)(6) and (f)(6)(i) with changes from the proposal and finalizing new paragraph (f)(7) to provide context and clarity regarding how CMS will implement and apply the regulations and also how MA organizations may implement and demonstrate compliance with the cost sharing limitations and protections adopted in this FC.

MA organizations are not expected to experience any greater burden when demonstrating compliance with the service category cost sharing standards in these regulations than MA organizations have had in the past when CMS reviewed MA plan benefit packages (PBPs) in the annual MA bids. Consistent with prior contract years, the PBP software includes validations to prevent an MA organization from entering cost sharing (coinsurance and copayment amounts) for a particular service category that is above the cost sharing limit. This process is expected to

be maintained in future years for service categories, using the coinsurance limits in these regulations and the copayment limits that CMS calculates applying the rules in these regulations. MA organizations must submit documentation (either with their initial bid or upon request) that clearly demonstrates how the copayment amount satisfies the regulatory requirements for each applicable plan where CMS has not calculated a copayment or coinsurance limit under these regulations and programmed the PBP with that limit. Next, we address how MA plans should:

(1) generally prepare and submit supporting documentation for the service category or for a reasonable group of benefits, if necessary; (2) calculate the estimated total MA plan financial liability for that contract year; (3) calculate the average Medicare FFS allowed amount for the plan service area; (4) modify supporting documentation for different provider payment structures; and (5) address three specific components of the supporting documentation that may be used to satisfy the regulatory requirements. Further guidance on these topics will be issued by CMS, as necessary.

For service categories where CMS does not calculate the specific copayment limits, each plan bid with a copayment for that benefit would need to be prepared and evaluated in relation to the estimated total MA plan financial liability for that contract year or the average Medicare FFS allowed amount for the benefit in the plan service area. Section 422.100(f)(6)(i) permits use of either of these. As discussed in sections II.B.5.b. and II.B.5.e. of this FC, paragraph (f)(6)(iii) requires use of only the estimated total MA plan financial liability for that contract year and § 422.100(j)(1) permits use of either set of data. We may request supporting documentation from the MA organization that shows how the plan's copayment amount satisfies the cost sharing standards finalized in paragraphs (f)(6) and (j)(1) as part of our evaluation of plan bids. The data MA organizations may use to develop supporting documentation for the cost sharing included in their PBP(s) are clarified in paragraphs (f)(6)(i), (iii)(B), and (j)(1)(ii) and are more completely discussed subsequently in this response. CMS, consistent with past years, will direct MA organizations through annual guidance, such as HPMS memoranda or bid instructions, on

whether supporting documentation must be submitted with their initial bid or submitted upon request depending on the service category. MA organizations must identify this documentation separately from other supporting documentation submitted as part of the BPT. MA organizations may include information for multiple plans in one set of documentation, but calculations must be presented for each plan individually (or plan segment, if applicable). The MA organization's calculations and documentation must reflect cost sharing amounts that combines the enrollee's entire cost sharing responsibility as a single, total copayment as finalized in §422.100(f)(9), even if the MA plan has contract arrangements involving separate payments to facilities and professional providers. This is consistent with our current practice of having MA organizations submit supporting documentation with the bid. For example, under current (contract year 2022) and previous policy, if an MA organization used copayments for the "DME – Equipment" service category and established a mandatory MOOP amount, it would have submitted supporting documentation in order to demonstrate how the copayment satisfied the cost sharing standards because only a coinsurance limit has been traditionally provided for that service category. This approach remains the same for contract year 2023 for the "DME – Equipment" service category and other DME service categories without final contract year 2023 copayment limits in Table 28. In addition, MA organizations with inpatient hospital acute and psychiatric and SNF coinsurance plan benefit designs in contract year 2022 and prior years submitted supporting documentation in order to demonstrate how their coinsurance met the cost sharing standards because we do not have a coinsurance limit for those service categories. This requirement also continues to apply for contract year 2023, as CMS has not included coinsurance limits for those service categories in the final contract year 2023 cost sharing limits provided in Table 28.

The February 2020 proposed rule noted that MA organizations must maintain (and provide to CMS upon request) supporting documentation for actuarial justifications for cost sharing, including the methods used in calculating the total MA plan financial liability. We

proposed that regardless of the type of cost sharing used, an MA plan must not pay less than a specified percentage of the total MA plan financial liability for in-network benefits in proposed § 422.100(f)(6)(i), (iii), and (j)(1)(iv). The February 2020 proposed rule stated that the term "total MA plan financial liability" means the total payment paid and includes both the enrollee cost sharing and the MA organization's payment. In this FC we modified paragraphs (f)(6)(i), (f)(6)(iii), and (j)(1)(ii) to use the term "estimated total MA plan financial liability for that contract year" to clarify that MA organizations may use more than one year of data to project this amount (following generally accepted actuarial principles and practices as required by paragraph (f)(7)). As a result of using this term consistently in the regulations, the mechanics of this process for calculating the copayment amount when CMS has not calculated an actuarially equivalent copayment limit are quite similar for paragraphs (f)(6)(i), (f)(6)(iii), and (i)(1). (The specified percentage of the estimated total MA plan financial liability for that contract year will vary based on the type of MOOP limit used by the plan for benefits subject to paragraph (f)(6)(iii).) For each provision, the copayment amount must be equal to, or less than, the copayment limit calculated by CMS or a dollar amount that is actuarially equivalent to a specified percentage of the estimated total MA plan financial liability for that contract year (or the average Medicare FFS allowable amount for the plan service area for benefits subject to paragraph (f)(6)(i) or (i)(1)). We are generally finalizing those polices, with some modifications as discussed throughout section II.B of this FC. As a result, in the absence of a copayment limit calculated by CMS, the MA plan must pay at least the specified percentage of the estimated total MA plan financial liability for that contract year or average Medicare FFS allowable amount (as applicable) for the service category or for a reasonable group of benefits in the PBP. We are finalizing explicit regulation text to be clear in paragraphs (f)(6)(i), (f)(6)(iii)(B), and (j)(1)(ii) what data the MA organization may use in calculating a dollar amount, if CMS does not calculate a copayment limit. It is not necessary for an MA organization to use one data source over the other (estimated total MA plan financial liability for that contract year or average

Medicare FFS allowable amount) when complying with § 422.100(f)(6)(i)(B) and (j)(1)(ii), which both provide the choice. However, as proposed and discussed in more detail in section II.B.5.b. of this FC, MA organizations must pay a minimum percentage of the estimated total MA plan financial liability for in-network basic benefits that are professional services; this necessarily means that in calculating copayment dollar amounts for service categories subject to paragraph (f)(6)(iii), the MA plans must use data about the estimated total MA plan financial liability for that contract year.

In response to the comment requesting that CMS allow the average contracted rate to be calculated at the parent organization level, we clarify here that MA organizations may use the estimated total financial liability for that contract year calculated at the MA plan level where this FC permits use of data about the MA plan's financial liability. A minority of MA organizations use segmented plans and, in those cases, the estimated total financial liability for that contract year would be calculated at the segment level (CMS will also complete the cost sharing evaluation at the segment level). However, in calculating actuarially equivalent copayment standards CMS will use aggregate (or nationally representative) projections from the OACT. In comparison, MA organizations will use aggregate payment data for their plan service area about the service category, or for a reasonable group of benefits, to which the cost sharing applies when determining the dollar figure that is actuarially equivalent to the coinsurance standard. Conducting the evaluation at the plan (or segment) level is the better policy, and the one we are finalizing here, as it: (1) reflects the cost sharing experienced by enrollees in the plan's service area; (2) protects against possible distortions from aggregating the average payment rate calculation across a larger organizational level that may not sufficiently reflect the plan's service area; and (3) coincides with the MA organization's provider contracts that may vary geographically. MA organizations that are new may calculate the estimated total MA plan financial liability for new plans based on projections of available provider contracts and expected enrollment trends for that contract year. In addition, MA organizations that are entering a new

service area may calculate the estimated total MA plan financial liability for that plan based on the total MA plan financial liability for the benefit in the organization's existing service area and also take into consideration projections of available provider contracts and expected enrollment trends in that new service area for that contract year. To address the potential that the MA organization may have insufficient data about the specific service area, CMS will implement and enforce the rules adopted in this FC to permit use of data on the MA plan financial liability that is not limited to the specific service area for new plans and new service areas.

For in-network benefits, the estimated total MA plan financial liability for that contract year is based on the provider contracting arrangements and expected enrollee utilization for the particular provider type and service. MA plans and their network providers negotiate payment arrangements without interference by CMS and may have varying enrollee utilization experience; CMS lacks information on those specifics and understands that plans may contract with providers through a variety of arrangements (such as, FFS, capitation, salary, or value-based arrangements). As a result, if CMS does not calculate a copayment limit for an in-network professional service category for a particular contract year, calculating a dollar amount that is actuarially equivalent to the coinsurance value will require analysis by the MA organization and that analysis must consider the various amounts that the MA plan expects to pay for that basic benefit in the applicable year. An MA organization may consider the various types of payment arrangements it has with network providers and aggregate this information to calculate a dollar amount that is actuarially equivalent to the applicable coinsurance limit for service categories subject to § 422.100(f)(6)(i), (iii), and (j)(1). In addition, an MA organization may weigh the aggregated data in calculating this dollar amount (that is, the actuarially equivalent value to the applicable coinsurance limit) using past utilization and variation of provider payments. For example, to comply with the requirements in paragraph (f)(6)(i) for in-network copayments, an MA organization may use their contracted payment rates for the providers that furnish the service(s) to determine the estimated total MA plan financial liability for those service(s); the

estimated total MA plan financial liability for that contract year is compared to the plan's cost sharing on a percentage basis to determine if the cost sharing exceeds an actuarially equivalent copayment amount to the 50 percent cost sharing standard. This process is consistent with the supporting documentation CMS has accepted in prior years.

For covered out-of-network basic benefits, the estimated total MA plan financial liability for that contract year must necessarily be based on the average Medicare FFS allowable amount for the plan service area because MA plans are required to ensure that out-of-network providers receive the Medicare FFS payment for the basic benefit that has been furnished to the enrollee. As a result, we are clarifying that, while § 422.100(f)(6)(i) describes the use of the estimated total MA plan financial liability for that contract year and the average Medicare FFS allowable amount, to comply with the requirement in paragraph (f)(6)(i) for out-of-network benefits, the plan must use the average Medicare FFS allowable amount for these determinations because the MA plan is required to pay, at a minimum, the Medicare FFS allowable amount for these benefits. If an MA organization is using copayment amounts for out-of-network services, the plan must use the average Medicare FFS allowable amount for all providers for the applicable service category or reasonable group of services in its plan service area as the basis for their calculations of the actuarially equivalent dollar amount. In addition, an MA organization may weigh the average Medicare FFS allowable amount using the plan's past utilization (such as including the Medicare FFS payment for each applicable provider type to administer the benefit) in calculating this dollar amount (that is, the actuarially equivalent value to the 50 percent coinsurance limit for out-of-network basic benefits). MA organizations establish cost sharing at the plan-level and we reiterate here that any calculations must be done at the plan (segment, if applicable) level to reflect the benefit design. This approach may be modified as necessary to comply with generally accepted actuarial principles and standards as described in paragraph (f)(7)(i). However, an MA organization that relies on paragraph (f)(7)(i) to use data and analyses from other than the plan's estimated total financial liability and service area must explain and support such a determination.

In summary, and as required by $\S 422.100(f)(6)$ and (j)(1) as finalized in this FC, MA organizations must establish either: (1) a coinsurance level that does not exceed the coinsurance percentage in the regulation; or (2) in the absence of a specific cost sharing limit calculated by CMS, a copayment that does not exceed the value that is actuarially equivalent to the specified percentage of the MA plan's estimated total financial liability for the benefit for that contract year (or the average Medicare FFS allowable amount for the plan service area for benefits subject to paragraph (f)(6)(i) and (j)(1)(i)). Specifically, to comply with paragraph (f)(6)(i), as well as demonstrate compliance, when CMS has not calculated a copayment limit, an MA organization must calculate the average Medicare FFS allowable amount of the plan service area or its estimated total MA plan financial liability for the service category or for a reasonable group of benefits or services covered under the plan in order to establish a maximum copayment amount (that is, dollar amount) that is actuarially equivalent to, or less than, 50 percent. If using copayments, the MA plan must use a copayment that is no greater than that maximum copayment amount. Similarly, as discussed in section II.B.5.e. of this FC, finalized paragraph (i)(1) provides that cost sharing established by the MA organization may not exceed the cost sharing required under original Medicare for the specified services; that means the cost sharing may be a copayment limit that is actuarially equivalent to the coinsurance used in original Medicare, which would be a dollar limit calculated by CMS or, if CMS did not calculate a copayment limit, a dollar limit calculated by the MA organization based on the average Medicare FFS allowable amount or the estimated total MA plan financial liability for that benefit in the plan's service area. The MA plan may have a copayment that is less than that maximum amount, but may not exceed that limit. As a result, the process MA organizations take to develop supporting documentation and to comply with paragraph (i)(1) when CMS has not calculated and issued a specific copayment limit is the same as for paragraph (f)(6)(i). The MA organization

must use the average Medicare FFS allowable amount for the plan service area, or the estimated total MA plan financial liability for the benefit in order to calculate and establish a copayment amount (that is, dollar amount) that is actuarially equivalent to, or less than, the cost sharing under original Medicare for the benefit. In order to be consistent in applying this approach for benefits that cannot exceed cost sharing under original Medicare, we are not finalizing part of proposed paragraph (j)(1)(iv) (which is otherwise finalized as paragraph (j)(1)(i)(D)) related to basing a copayment on the total MA plan financial liability for home health services. The policies being finalized at § 422.100(j)(1) are more completely discussed in section II.B.5.e. of this FC. In addition, to comply with paragraph (f)(6)(iii) in situations where CMS has not calculated and issued a copayment limit for a particular service category, an MA organization must calculate an actuarially equivalent copayment amount to ensure that the MA organization does not pay less than the specified percentage of the estimated total MA plan financial liability for the applicable type of MOOP limit. This will allow MA plans to establish a copayment amount for a professional service category that is equal to or less than an actuarially equivalent value to the coinsurance limit required by paragraph (f)(6)(iii) based on the estimated total MA plan financial liability for the benefit. An MA organization is not required to ensure that every service for every enrollee meets the requirement that the MA plan pay no less than the specified percentage of the estimated total MA plan financial liability for that contract year when the MA organization is using copayment structures.

CMS's evaluations for purposes of determining compliance with § 422.100(f)(6) and (j)(1), if CMS has not published a copayment standard (or coinsurance limit for inpatient hospital standards set in paragraph (f)(6)(iv)), will align with OACT bidding guidance³⁶ and follow generally accepted actuarial standards of practice in accordance with paragraph (f)(7)(i). The estimated total MA plan financial liability for that contract year and Medicare FFS allowed

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³⁶ The annual OACT MA bidding guidance may be accessed from CMS's page on Bid Forms & Instructions from the website: https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Bid-Forms-Instructions.

amount should consider credibility based on OACT bidding guidance and be adjusted to meet actuarial principles and practices. In addition, copayment amounts will be calculated using the rounding rules finalized in paragraph (f)(6)(ii). This approach to develop and evaluate supporting documentation is consistent with current OACT bidding guidance, supports cost sharing stability for beneficiaries, and allows MA organizations to establish plan benefit structures that incorporate copayments. We acknowledge that MA organizations may have different provider arrangements (for example, fee-for-service and capitation) so determining that an in-network copayment amount is not more than the specified coinsurance percentage of the estimated total MA plan financial liability for the applicable service category may require planspecific approaches; we expect to take this into account when determining if an MA plan's (or segment-level) cost sharing complies with paragraphs (f)(6)(i), (f)(6)(iii), and (j)(1). In evaluating an MA organization's supporting documentation for service categories subject to paragraphs (f)(6)(i), (iii), and (j)(1), CMS may accept information that considers the MA plan's estimated total financial liability for that contract year using these provider payment arrangements or a combination of these arrangements, as long as it is reflects the plan's service area (or the service area of a segment). For example, if upon request, the MA organization submits supporting documentation at the contract level with sufficient actuarial justification, instead of calculating at the plan level (such as, unique provider payment arrangements), CMS will take this under consideration. Likewise, if CMS were to request an MA organization to provide a justification for the copayment included in their contract year 2023 PBP for Medicarecovered podiatry (which is subject to § 422.100(f)(6)(i) and lacks a CMS set copayment limit for contract year 2023 as it is not included in Table 28), we may consider actuarial justifications that are specific to and reflect capitated payment arrangements with different providers (and different types of providers) that furnish Medicare-covered podiatry services, if applicable.

Because the analyses performed by MA organizations must use generally accepted actuarial principles and practices pursuant to § 422.100(f)(7)(i), supporting documentation must

be consistent with generally accepted actuarial principles and practices. The MA organization's analysis must demonstrate how plan cost sharing complies with the regulations in § 422.100(f)(6)(i), (iii), and (j)(1). As a result, the documentation must demonstrate:

- How the MA organization calculated the plan's estimated total financial liability for the benefit for that contract year (or the average Medicare FFS allowable amount for the service area for benefits subject to $\S 422.100(f)(6)(i)$ and (j)(1));
- The percentage the copayment represents of the plan's estimated total financial liability for the benefit for that contract year (or the average Medicare FFS allowable amount for the service area for benefits subject to § 422.100(f)(6)(i) and (j)(1)); and
- How the cost sharing does not exceed, as applicable, an actuarially equivalent amount to the 50 percent estimated total MA plan financial liability requirement (established at § 422.100(f)(6)(i)), the range of cost sharing requirement based on the type of MOOP limit (established at paragraph (f)(6)(iii)), and cost sharing under original Medicare (established at § 422.100(j)(1) and (2)).

MA organizations must develop and maintain documentation that demonstrates how plan cost sharing satisfies the estimated total MA plan financial liability for that contract year and average Medicare FFS allowable amount requirements and other applicable cost sharing coinsurance limits for covered benefits. If CMS requests information as part of bid review or general oversight of the plan's copayment or coinsurance amounts for specific service categories, an MA organization may submit an analysis that addresses each of the three components described previously, or use a PMPM analysis that addresses multiple components simultaneously. For example, the copayment may be represented as a percentage of the estimated total MA plan financial liability for that contract year or the average Medicare FFS allowed amount for the benefit. If necessary, we expect that supporting documentation and data may include information on provider payments or costs, enrollee enrollment and utilization, and cost sharing paid by enrollees (both in terms of dollar figures and as a percentage of the estimated total MA

plan financial liability for that contract year or average Medicare FFS allowable amount for the benefit) to demonstrate how the plan's cost sharing amounts satisfy requirements being finalized in this rule. We provide in Table 11 an illustration of one way an MA organization can approach developing and summarizing supporting documentation that addresses the three components described previously for some select service categories. We would expect MA organizations to also include any necessary payment, cost, and/or utilization data or assumptions. Requiring supporting documentation as described in this response protects enrollees from high cost sharing (generally and in relation to specific service categories, such as physical therapy and speech-language pathology, as summarized in section II.B.5.b. of this FC) by ensuring that MA plan copayments satisfy cost sharing requirements in various scenarios.

TABLE 11: GENERAL ILLUSTRATION OF SUMMARY OF SUPPORTING DOCUMENTATION FOR AN MA PLAN WITH A LOWER MOOP LIMIT TO EVALUATE COMPLIANCE WITH §§ 422.100(f)(6)(i), 422.100(f)(6)(iii)(C), AND 422.100(j)(1)

Plan ID	PBP Service Category	Cost Sharing Standard	Estimated Total MA Plan Financial Liability ¹	PBP Cost Sharing	Percent of Estimated Total MA Plan Financial Liability ¹	Pass/Fail Test
H0000-001-1	DME - Equipment	50%2	\$100	\$30	30%	PASS
H0000-001-2	Example Service Category A	50%3	\$100	\$75	75%	FAIL
H0000-001-3	Example Service Category B	20%4	\$250	\$45	18%	PASS

¹ The Medicare FFS allowed amount for the benefit may also be used for service categories subject to § 422.100(f)(6)(i) and (j)(1) and must be an average for the plan service area. The estimated total MA plan financial liability for that contract year and Medicare FFS allowed amount should consider credibility based on OACT bidding guidance and be adjusted to meet actuarial principles and practices.

CMS intends to work with MA organizations when requesting supporting documentation to address any unique situations and ensure calculations and subsequent evaluations comply with generally accepted actuarial principles and standards. We may also provide additional information on how MA organizations should prepare their cost sharing supporting documentation and data (such as, potential formats and information to be included in

² For MA plans with a lower MOOP limit, the cost sharing limit for the "DME – Equipment" service category is 50% in accordance with § 422.100(f)(6)(i) and (j)(1).

³ For MA plans with a lower MOOP limit, the cost sharing limit for the "Example Service Category A" is 50% coinsurance in accordance with § 422.100(f)(6)(iii).

⁴ The cost sharing limit for the "Example Service Category B" is 20% coinsurance in accordance with § 422.100(j)(1).

documentation) through instructions, such as HPMS memoranda or bidding instructions. Individuals and organizations may request placement on the HPMS listserv at https://hpms.cms.gov/app/ng/home/ to ensure that they receive HPMS memoranda.

Comment: A commenter requested CMS make the 50 percent total financial liability determination subject to the nearest \$5 rounding rule, proposed at § 422.100(f)(6)(ii)(A), to help with year over year benefit design stability.

Response: Having MA plans apply the same rounding methodology specified in § 422.100(f)(6)(ii) does not appear to result in any harm, especially as CMS will be using those rounding rules for calculating cost sharing limits. In addition, applying the same rounding rules to calculate actuarially equivalent copayment values regardless if the calculations are completed by CMS or by an MA organization will promote consistency in determining compliance with the regulatory standards being set through this FC. Accordingly, we are finalizing here that MA organizations will use the rounding rules in paragraph (f)(6)(ii) when calculating actuarially equivalent cost sharing values for the regulatory standards in § 422.100(f)(6), (f)(7), and (j)(1). This will allow MA organizations to round to the nearest \$5 increment (or lower \$5 increment where the amount is exactly between two increments) when calculating an actuarially equivalent copayment for benefits that must satisfy the 50 percent coinsurance obligation under paragraph (f)(6)(i), professional services subject to paragraph (f)(6)(iii), and benefits listed in paragraph (i)(1)(i). In addition, MA plans may round to the nearest whole \$1 for out-of-network inpatient acute and psychiatric and skilled nursing facility cost sharing, also rounding down when the actuarially equivalent copayment is projected to be exactly between two increments, when calculating values that comply with paragraph (f)(6)(iv). This rounding rule for inpatient hospital cost sharing was proposed in paragraph (f)(6)(ii)(A) and is finalized generally as proposed in paragraph (f)(6)(ii)(B). As finalized, paragraph (f)(6)(ii) is clear that the rounding rules will be used in calculating copayment limits and evaluating whether an MA plan's cost sharing complies with the cost sharing limits.

Based on the changes to $\S 422.100(f)(6)(i)$ and new paragraph (f)(7), the transition schedule we are adopting in new paragraph (f)(8), and changes we are finalizing in § 422.100(j) (as discussed in section II.B.5.e. of this FC), we are finalizing proposed paragraph (f)(6)(ii) with modifications. First, as finalized, paragraph (f)(6)(ii)(A) will apply the \$5 rounding rules proposed for professional service categories and benefits that are subject to § 422.100(f)(6)(i), (f)(6)(iii), and (j)(1)(i). As a result, in calculating copayment limits and in evaluating an MA plan's compliance with paragraphs (f)(6)(i), (f)(6)(iii), and (i)(1), CMS will round to the nearest whole \$5 increment. The exception to this is copayments for inpatient hospital acute and psychiatric and SNF services, where paragraph (f)(6)(ii)(B) explicitly provides that the \$1 rounding rule applies. In addition, MA plans that calculate actuarially equivalent copayments values because CMS has not calculated a copayment limit will round to the nearest whole \$5 increment for service categories for which paragraph (f)(6)(ii)(A) applies. For cases in which the copayment limit is projected to be exactly between two increments, the final actuarially equivalent copayment value is rounded (by CMS and by MA plans) to the lower dollar amount. Consistent with current practice, this application of the rounding rules does not prevent an MA plan from establishing a copayment that is not a \$5 increment. For example, if CMS does not set a copayment limit for a service category subject to paragraph (f)(6)(iii), an MA organization may choose to establish a \$13 copayment if, in following the rules in paragraph (f)(6)(ii) and (f)(6)(iii), the calculations of an actuarially equivalent value to the applicable coinsurance standard equaled \$12.52, rounded to \$15. This ensures consistency in how actuarially equivalent copayment values are calculated using the rounding rules while maintaining flexibility for MA organizations to establish copayments below the actuarially equivalent value. In comparison, if CMS had the same result in calculating an actuarially equivalent copayment for a service category subject to paragraph (f)(6)(iii), \$12.52, rounded to \$15, we would issue the copayment limit at the \$5 increment, or \$15. Second, we added references to paragraphs (f)(6)(iv) and (i)(1)(i)(C) to paragraph (f)(6)(ii)(B) to clarify which regulations are subject to the inpatient

hospital cost sharing rounding rules. Third, in making these changes we added introductory language to paragraph (f)(6)(ii) and reorganized (f)(6)(ii) for clarity. As a result, the proposed requirement in paragraph (f)(6)(ii)(B) that the actuarially equivalent copayment value is rounded down to the lower dollar amount is finalized generally as proposed in paragraph (f)(6)(ii)(C). Fourth, as discussed in a prior response to comment in this section, new paragraph (f)(7) codifies the use of actuarial principles and practices and the requirements to calculate actuarially equivalent copayment limits. To ensure these requirements are applied consistently with the proposed rounding rules, § 422.100(f)(7)(ii)(E) refers to paragraph (f)(6)(ii) as part of the steps for CMS calculation of copayment limits. Fifth, as discussed in section II.B.5.b. of this FC, we are adopting a transition schedule for certain cost sharing standards; we are finalizing a reference to that schedule (which is in paragraph (f)(8)) in paragraph (f)(6)(ii) to clarify that the rounding rules will be used for those transitional copayment limits as well.

Comment: A commenter encouraged CMS to codify an explicit requirement for MA organizations to demonstrate compliance with the regulation standards proposed at § 422.100(f)(6) by providing CMS with information substantiating their contracted rates for professional services and their cost sharing limits for basic benefits.

Response: CMS thanks the commenter for their feedback. In this FC, we are not adopting an explicit regulatory provision to require MA organizations to demonstrate compliance with the regulation standards in § 422.100(f)(6), as we believe that CMS's bid review processes will generally address this and that CMS's oversight and monitoring authority would support any requests for information and necessary documentation from MA organizations. Compliance program, record keeping, audit and access requirements in §§ 422.503 and 422.504, in conjunction with longstanding bid review policy, adequately establish CMS's authority to investigate compliance with the MA program and benefit requirements adopted in this FC. In addition, the regulation at § 422.254(b)(5), (c)(5), and (c)(6) requires that MA organization bid submissions for coordinated care plans, including regional MA plans and specialized MA plans

for special needs beneficiaries (described at § 422.4(a)(1)(iv)), and for MA private fee-for-service plans must be prepared in accordance with CMS actuarial guidelines based on generally accepted actuarial principles and must include the actuarial bases of the bid, a description of cost sharing applicable under the plan, and the actuarial value of the cost sharing. If we find, through future bid review or general oversight activities, that greater clarification in regulatory text in needed, we will pursue future rulemaking.

In general, MA organizations are required to provide CMS with information that demonstrates how their bid and plan design (including coinsurance or copayment amounts) satisfy the regulatory requirements, if necessary as part of CMS's bid review process or at any time during the year for general oversight activities. For example, for MA plans that choose to establish a coinsurance cost sharing for inpatient hospital scenarios or SNF service categories, CMS will typically use plan information to evaluate, consistent with current practice, whether the coinsurance exceeds the applicable copayment dollar amounts calculated and issued for that contract year. This evaluation is based on actuarial information and analyses.

b. Range of Cost Sharing Limits for Certain Outpatient and Professional Services (§ 422.100(f)(6)(iii) and (f)(8))

Comment: Comments were mixed regarding CMS's proposal to codify the methodology used to set the MA cost sharing standards for professional services and to establish a range of cost sharing limits for benefits furnished on an in-network basis, based upon the type of MOOP limit established by the MA plan. A commenter supported differentiating cost sharing limits based on the plan's MOOP limit and requested CMS better differentiate the maximum copayment limits between the voluntary and mandatory MOOP limits for primary care physician (PCP), physician specialist, emergency/post-stabilization services, and home health services. The commenter stated that currently, the maximum copayments for the "PCP" and "physician specialist" service categories are the same under the voluntary and mandatory MOOP limits set by CMS. The commenter stated that CMS should make greater differentiation in the cost sharing

levels for service categories for the various MOOP limits, especially for those services that have higher utilization rates (which will increase the actuarial value of the copayments). The commenter stated that these changes would make it more likely that an MA plan would choose to offer the voluntary MOOP limit.

Response: We appreciate the commenters' feedback on our proposal at § 422.100(f)(6)(iii). We do not believe that it is necessary to finalize a more significant difference between the cost sharing levels permitted for each MOOP type in paragraph (f)(6)(iii). We proposed a 10-percentage point difference between the coinsurance levels based on the type of MOOP limit and thus sufficiently differentiated cost sharing limits for these categories without creating potentially discriminatory cost sharing for beneficiaries. As discussed in the February 2020 proposed rule, we arrived at the specified percentages of 30 percent, 40 percent, and 50 percent for the underlying benefit, tied to use of the mandatory (highest), intermediate, and lower MOOP limits, by assigning the highest coinsurance amount that we believe is not discriminatory (50 percent) to the lowest MOOP limit; and 30 percent coinsurance (which is most closely related to copayment limits from prior contract years) to the mandatory MOOP limit, to balance the MA plan's incentives to use each type of MOOP limit. Then, we established the midpoint (40 percent) for the intermediate MOOP limit. By establishing these limits to range from the highest amount, we will permit cost sharing amounts the MA market is used to from prior contract years for several service categories. Our intention is to balance several goals: (1) protect beneficiaries from discriminatory cost sharing amounts; (2) avoid disruptive changes in MA plan designs; and (3) create cost sharing standards that would result in a clear increase in MA organization financial responsibility for professional services if the MA plan establishes a mandatory MOOP limit rather than a lower or intermediate MOOP limit.

We agree with the commenter that increasing the number of service categories for which cost sharing limits can be differentiated by the type of MOOP limit from prior contract years may be an incentive for MA organizations to offer lower MOOP limits. We also believe

differentiating these cost sharing limits may encourage innovative plan designs, such as those that are trying to improve health care outcomes. This may include changing cost sharing for certain service categories to encourage enrollees to seek preventive health care or high-value services. CMS supports value-based insurance design and expects that providing increased flexibility in plan designs, within non-discriminatory cost sharing ranges, will encourage competition and innovation by MA plans. However, we do not believe that a greater number of differentiated service categories would necessarily increase the actuarial value of cost sharing for that plan's benefit design. The actuarial value of the plan's cost sharing depends on the given benefit compared to other benefits. If a service type with a lower amount of cost sharing has a high rate of utilization, then that would likely lower the plan's actuarial value of cost sharing. For example, if an MA plan establishes a mandatory MOOP limit which has lower cost sharing standard amounts compared to prior contract years across a number of service categories then the plan may have a lower actuarial value of cost sharing. Finally, MA organizations establish cost sharing amounts based on a number of factors such as competition, provider contracts, and needs of beneficiaries in their service area. While CMS can set cost sharing requirements to discourage discrimination against beneficiaries with high health care needs and encourage MA plans to lower the financial burden on enrollees, we do not believe CMS should dictate identical cost sharing for all basic benefits for all MA plans and we did not propose to do so in this rulemaking.

Comment: A commenter stated doctors of optometry may be considered a "physician specialty" or a "primary care physician" for the purpose of the cost sharing limits set in this FC, but noted their preference was the primary care category to ensure the lower cost sharing limit would apply to prevent financial barriers hindering beneficiary access to needed eye care. This commenter explained that doctors of optometry play an important role in patient care with respect to general health and the management of systemic diseases with ocular manifestations and as such, provide primary care.

Response: For purposes of the PBP, the longstanding practice has grouped doctors of optometry (namely, specialties of ophthalmology and optometry) with physician specialties and CMS expects to maintain this approach in future years. In addition, applying the copayment limits calculated for the "physician specialist" service category to doctors of optometry is consistent with the current network adequacy requirements (in that doctors of optometry are not used to determine if a plan's provider network for primary care services is sufficient). As a result, we are not implementing the recommendation that we characterize optometry services as primary care services in this FC for purposes of applying § 422.100(f)(6)(iii). We note the current (and longstanding) service category description of primary care services in the PBP is as follows:

Internal Medicine, General Practice, or Family Practice Services provided by a medical doctor or a doctor of osteopathy: General Physicians' services are the professional services performed by a physician for a patient including diagnosis, therapy, surgery, consultation, and care plan oversight. The services must be rendered by the physician or incident to physician's services. A service may be considered to be a physician's service where the physician either examines the patient in person or is able to visualize some aspect of the patient's condition without the interposition of a third person's judgment. Direct visualization would be possible by means of X-rays, electrocardiogram and electroencephalogram tapes, tissue samples, telecommunications, etc. References: 42 CFR 410.10 and 410.26 and the Medicare Benefit Policy Manual, Chapter 15.

Original Medicare does not currently cover eye exams furnished by optometrists. However, original Medicare does cover some other services that may be provided by optometrists, such as screening for glaucoma.

We may change the list of provider specialties that are used to calculate actuarially equivalent copayments in future years and would generally describe such a change in the annual guidance required by § 422.100(f)(7)(iii). For example, in this FC, we are modifying the data used to calculate the final contract year 2023 copayment limits for the "primary care physician" and "physician specialist" service categories to better align the applicable provider specialties for

these categories with network adequacy standards and typical standards of care. In the February 2020 proposed rule, we described using the following provider specialty types to calculate a copayment limit for the "physician specialist" and "primary care physician" service categories:

- Physician Specialist: Cardiology; Geriatrics; Gastroenterology; Nephrology; and Otolaryngology (ENT)
- Primary Care Physician: Family Practice; General Practice; and Internal Medicine These groupings of provider specialties do not exactly match the list of provider specialties that are used to determine provider network adequacy for the same professional service categories. Currently, network adequacy requirements only allow MA plans to list credentialed providers for the following specialties to count towards meeting our standards for primary care providers: General Practice, Family Practice, Internal Medicine, and Geriatrics³⁷. Considering how provider or facility-specialty types may change for a network adequacy evaluation annually (as discussed in the January 2021 Final Rule and codified in § 422.116(b)(3)), we believe maintaining a certain level of flexibility to add or remove a provider specialty type in the calculations of actuarially equivalent copayment limits will ensure copayment limits reflect the providers the cost sharing is applied to. CMS's current position is that the geriatrics provider type furnishes services that we would consider as primary care rather than a specialist and geriatricians are responsible for the whole patient. Usually, specialists treat a limited disease area, often with a limited patient population. In addition, provider specialists often have equipment and perform procedures that support diagnoses in the disease domain in which they specialize. In general, provider specialists are not responsible for general preventive services and screening. As a result of these considerations, we are using the following provider specialty types to calculate the final contract year 2023 copayment limits for the "physician specialist" and "primary care physician" service categories in this FC:

³⁷ See the HSD reference file for the: https://www.cms.gov/medicare/medicare-advantage/medicareadvantageapps. In the June 2020 final rule (85 FR 33853), CMS identified the types of providers considered primary care providers by reference to the HSD reference file as well.

- Physician Specialist: Cardiology; Gastroenterology; Nephrology; Otolaryngology
 (ENT)
- Primary Care Physician: Family Practice; General Practice; Internal Medicine;
 Geriatrics

Although we are including flexibility to use a slightly modified list of provider specialties, the rules in this FC for the process and methodology for calculation of the actuarially equivalent copayment limits, which are generally as proposed, will continue to apply in future years. The final contract year 2023 in-network copayment limits for the "primary care physician" and "physician specialist" service categories in Table 28 reflect this update as well as the changes in implementing the range of cost sharing limits proposed, as discussed in a subsequent response to comment in this section, and use of contract year 2023 Medicare FFS data projections (based on 2017 – 2021 Medicare FFS data). Finally, moving the "geriatrics" provider specialty to inform the calculations of an actuarially equivalent copayment for the "primary care physician" service category did not, in itself, produce significant changes in comparison to the illustrative copayment limits for both of the "primary care physician" and "physician specialist" service categories from the February 2020 proposed rule. If we had used these different lists of provider specialties to calculate the illustrative copayment limits provided in Table 5 in the February 2020 proposed rule, the only difference in those copayment amounts would have been the illustrative copayment for the "physician specialist" service category for the lower MOOP limit; using this different list of provider specialties, the actuarially equivalent copayment value to 50 percent coinsurance for the lower MOOP limit would have increased from \$80 to \$85 after application of the proposed rounding rules in that table.

<u>Comment:</u> A commenter requested that CMS implement the proposal of establishing a range of cost sharing limits for professional services (in § 422.100(f)(6)(iii)) over several years to reduce disruption in the market and for beneficiaries. This commenter noted that because MA plans are still going to be required to satisfy the Total Beneficiary Cost (TBC) standard,

requiring plans with a mandatory MOOP limit to meet these new cost sharing standards in a single year could prove to be very disruptive. The commenter stated that MA plans will be forced to make drastic changes on short notice, which, in some cases, would cause some plans to be non-renewed. In addition, the commenter provided an example of a schedule to implement a multiyear phase-in of the policy in paragraph (f)(6)(iii). This example, illustrating a multiyear transition to reach the proposed range of cost sharing by the type of MOOP limit by 2025, is presented in its entirety as Table 12, "Example of a Multiyear Phase-in for Cost Sharing Limits Based on the MOOP Type." In the commenter's example, the lower MOOP retains the 50 percent cost sharing limit we currently use (and proposed for MA plans that use the lower MOOP limit) while the cost sharing limit tied to the mandatory MOOP limit decreases from the current level of 50 percent by 5 percentage points annually until it reaches 30 percent; under this example, the cost sharing limit tied to the intermediate MOOP limit is calculated as the percentage that is the mid-point of the other two MOOP limits, which is consistent with our proposed approach for MA plans that use the intermediate MOOP limit.

As referenced in other comment summaries in this section and in sections II.B.5.d and e. of this FC, several commenters were also concerned about the proposed level of allowable cost sharing overall or for specific service categories (including the "dialysis services" and "physical therapy and speech-language pathology" service categories). For the "physical therapy and speech-language pathology" service category, a commenter on that topic was similarly concerned about the projected increase in the copayment limit from contract year 2021 limits being unreasonably high for enrollees.

TABLE 12: EXAMPLE OF A MULTIYEAR PHASE-IN FOR COST SHARING LIMTS BASED ON THE MOOP TYPE

MOOP Level	2021	2022	2023	2024	2025
Lower	50%	50%	50%	50%	50%
Intermediate		47.5%	45%	42.5%	40%
Mandatory	50%	45%	40%	35%	30%

Response: We appreciate the concerns about providing time for MA organizations to adjust to the new cost sharing limits to minimize potential market and beneficiary disruption and agree that a transition over several years to the new cost sharing limits is appropriate. In this response we explain the changes CMS is making to address the commenter's concerns and additional changes that impact our proposals in § 422.100(f)(6)(iii) in order to comprehensively present the finalized requirements. As discussed in section II.B.5.a. of this FC in relation to new § 422.100(f)(7), we are consolidating and clarifying the data and requirements CMS uses to calculate copayment limits for service categories subject to § 422.100(f)(6)(i), (f)(6)(iii), and (j)(1). As a result, we are finalizing proposed paragraph (f)(6)(iii) with modifications to incorporate references to paragraph (f)(7) as well to include new transition provisions.

We proposed and are finalizing that the cost sharing for in-network basic benefits that are professional services must not exceed specific coinsurance thresholds and actuarially equivalent copayment values, with those cost sharing thresholds tied to the type of MOOP limit used by the MA plan; in addition, the MA plan must not pay less than an identified percentage of the estimated total MA plan financial liability for these basic benefits for that contract year. We are finalizing a schedule for implementing the use of the 30 percent, 40 percent, and 50 percent cost sharing limits for use of the mandatory, intermediate and lower MOOP limits; that transition will be from 2023 through 2026 and is finalized in paragraphs (f)(6)(iii)(C) through (F). We are also finalizing an additional provision in new paragraph (f)(8) to limit increases to copayment limits calculated by CMS over the same transition period from 2023 to 2026. New paragraph (f)(8) will control how CMS calculates and issues copayment limits in order to transition from contract year 2022 copayment limits to values that are actuarially equivalent to the range of coinsurance limits that are finalized in paragraph (f)(6)(iii)(F) for contract year 2026. When CMS does not calculate the copayment limit for a professional service category, MA organizations must follow the transition schedule in paragraphs (f)(6)(iii)(C) through (F) for both coinsurance and copayments. In addition, we are finalizing a provision to more clearly address in paragraphs

(f)(7) and (f)(8)(ii)(D) the specific methodology CMS will apply, in using the data described in proposed paragraph (f)(6)(iii)(B), to calculate copayment limits. The new provisions provide more detail, which we believe was implicit in the descriptions in the preamble of the February 2020 proposed rule but is better stated in the regulation text. Under this FC, the cost sharing limits set in paragraph (f)(6)(iii) are subject to new paragraph (f)(7). Overall, the changes from our February 2020 proposed rule regarding the limits on cost sharing for professional services that are basic benefits are to include transition provisions (for both coinsurance limits and copayment limits) and to more explicitly address the data and standards used to calculate values for copayment limits that are actuarially equivalent to the coinsurance limits.

We are finalizing § 422.100(f)(6)(iii)(A) substantially as proposed to prohibit MA plans from having cost sharing for in-network basic benefits that exceeds the limits in paragraph (f)(6)(iii) for the MOOP limit established by the plan, with a correction to reference paragraph (f)(6)(iii) as intended. We note this change does not affect how the rounding rules in paragraph (f)(6)(ii) will be applied to copayments for professional services. (Section II.B.5.a. of this FC discusses how the rounding rules are being finalized substantially as proposed.) Proposed paragraph (f)(6)(iii)(B) identified the data that CMS would use when calculating the cost sharing limits for in-network basic benefits that are professional services but as finalized specifies the rules for calculating copayment limits. In revising paragraph (f)(6)(iii)(B) to be subject to paragraph (f)(7), the standard for the data that CMS may use is now addressed in paragraphs (f)(7)(ii)(A) and (B). Specifically, CMS will use Medicare FFS data projections (as defined in paragraph (f)(4)(i) and discussed in detail in section II.A.4.b. of this FC) which includes cost and utilization data from beneficiaries with and without ESRD. In addition, CMS may use available MA encounter data if available and where appropriate (which is codified in paragraph (f)(7)(ii)(B)). While we only proposed use of MA encounter data in calculating cost sharing for inpatient services, we believe that it is appropriate to also permit use of MA encounter data for calculating other cost sharing in order to consider utilization differences between Medicare FFS

beneficiaries and MA enrollees; these utilization differences may be useful to reach an amount that most closely reflects an actuarially equivalent copayment to the applicable coinsurance percentage for the service category and beneficiary population. For example, if the utilization of different physician types (such as, physical therapists compared to speech-language pathologists) was significantly different between Medicare FFS and MA encounter data, we may consider weighting Medicare FFS cost data by utilization reflected in available MA encounter data for the relevant facility and provider types in order to reach a copayment value that is most closely actuarially equivalent to what MA enrollees may typically experience at the applicable coinsurance level for the type of MOOP limit. CMS did not apply any MA encounter utilization data in our calculations to reach the final contract year 2023 copayment limits shown in Table 28. However, we believe that this is an important flexibility for ensuring that copayment limits are actuarially equivalent to the maximum coinsurance percentages set in the regulation. In addition, using MA encounter utilization data in this manner may be one of the topics on which we could solicit comment through the subregulatory process finalized in paragraph (f)(7)(iii) for contract year 2024 and future years. Finally, use of MA encounter data will also be limited to the encounter data that is available at the time of the necessary analyses and projections and appropriate for that use. Per § 422.310(g), MA organizations generally have until the January 2 years after the year in which an encounter occurred to submit all encounter data. As a result, this timeframe means that CMS does not always have complete years of MA encounter data that is as recent as the Medicare FFS claims data CMS will use in calculating MOOP and cost sharing limits. We will consider factors like this when deciding whether and when it is appropriate to use MA encounter data and whether sufficient MA encounter data is available to be used in calculating copayment limits under this FC.

CMS is also modifying the cost sharing regulations to clarify that the cost sharing limits may be a coinsurance limit or a copayment limit that is an actuarially equivalent dollar amount to the applicable coinsurance limit (subject to § 422.100(f)(7) and (8)) and clarify that the

copayment limits may be calculated by CMS, or, if CMS does not calculate a copayment limit, the MA plan must establish a copayment that does not exceed the actuarially equivalent dollar amount to the applicable coinsurance limit. This is also discussed in section II.B.5.a. of this FC in relation to finalized paragraph (f)(6)(i). To be clear on this point in relation to cost sharing limits for professional services, we are finalizing new text in paragraph (f)(6)(iii)(B). We also clarify that where CMS does not calculate a copayment limit, finalized paragraph (f)(6)(iii)(B) nonetheless requires that the copayment amount used by the MA plan not exceed the actuarial equivalent of the coinsurance percentage, based on the estimated total MA plan financial liability for that benefit and contract year. While the proposed regulation text stated an absolute requirement in paragraphs (f)(6)(iii)(C)(1) through (3) that MA plans must pay not less than the specified percentage, we believe that additional clarity on this point improves the regulation. Under this FC, the copayment limits calculated by CMS take precedence but CMS does not intend to calculate and issue copayment limits for every imaginable benefit covered by Parts A and B. As discussed in section II.B.5.a. of this FC, new paragraphs (f)(7)(i) and (ii) codify how CMS uses Medicare FFS data projections in accordance with generally accepted actuarial principles and practices when calculating actuarially equivalent copayment values when multiple approaches are available. Referencing paragraph (f)(7) in paragraph (f)(6)(iii)(B) makes clear in the regulation that: (1) these standards apply to the copayment limits CMS calculates for professional services for contract year 2023 and subsequent years; and (2) the copayment limits will be updated annually based on the Medicare FFS data projections. In addition, the reference to paragraph (f)(8) in paragraph (f)(6)(iii)(B) applies the limit on increases to copayment limits and the copayment transition for how CMS calculates copayment limits for these professional services (discussed in more detail subsequently in this response). Paragraphs (f)(4)(i), (f)(6)(iii)(B), (f)(7), and (f)(8) together describe the Medicare FFS data projections and the process CMS uses in calculating cost sharing limits for professional services. Further, the process of identifying the data to be used will be subject to new paragraph (f)(7)(i) and its

requirement to use actuarial principles and practices in calculating copayment limits under paragraphs (f) and (j).

As discussed in section II.B.5.a. of this FC, in relation to new § 422.100(f)(7)(i) and (ii), CMS intends to only issue and maintain copayment limits for service categories subject to § 422.100(f)(6) and (j)(1) when: (1) an actuarially equivalent copayment can be calculated using Medicare FFS data projections available to CMS and using generally accepted actuarial principles and practices; and (2) CMS believes calculating such a copayment limit is appropriate to carry out program purposes, including setting copayment limits that most closely reflect an actuarially equivalent copayment for the benefit and beneficiary population, protecting against discriminatory cost sharing, and avoiding unnecessary fluctuations in cost sharing that may confuse beneficiaries. Where CMS does not calculate the copayment limit, MA organizations must establish copayment amounts that comply with paragraph (f)(6)(iii) based on their estimated total MA plan financial liability for the benefit for that contract year. In doing so, MA organizations may use their data about cost and utilization of the relevant services in the plan (or segment, if applicable) and must also use generally accepted actuarial principles and practices. A decision by CMS not to calculate a copayment limit applying the rules in paragraphs (f)(6), (7), and (8) for a particular year will not prevent CMS from calculating and issuing the copayment limit in future years. Because paragraph (f)(6)(iii) purposefully does not include a complete list of professional services that are basic benefits, but is rather representative of examples of professional services. CMS may need to request supportive documentation from MA organizations regarding various covered services in cases where an MA plan has calculated an actuarially equivalent value to establish the copayment for a particular service. We note instructional guidance is provided in section II.B.5.a. of this FC on how MA organizations can prepare supporting documentation for copayments subject to paragraph (f)(6)(iii). Next, we discuss the commenter's specific recommendation to conduct a multiyear transition to reach the proposed range of cost sharing by the type of MOOP limit by contract year 2025.

We agree with the commenters that CMS should minimize potential market and beneficiary disruption as we shift away from cost sharing limits that have not been updated in recent years to the cost sharing limits we proposed and are finalizing. In addition, as we considered our proposal to make annual changes to the copayment limits for professional services based on updated Medicare FFS data projections, we examined how other policies proposed and finalized in § 422.100(f)(4) through (f)(6) include protections to guard against volatility and significant changes from one year to the next. For example, we structured the proposals in sections VI.A. and B. of the February 2020 proposed rule to transition changes, such as the proposed multiyear incorporation of ESRD costs into the methodology that CMS uses to calculate MOOP and inpatient hospital cost sharing limits. We also proposed, and are finalizing with modifications (as discussed in section II.A. of this FC), guardrails in paragraph (f)(4)(iv) and (f)(4)(v) to limit the amount of change from one year to the next in the MOOP limits. CMS's goal is to provide MA organizations the flexibility to design stable benefit structures from 1 year to the next as well as ensure that enrollee cost sharing does not discriminate against beneficiaries with high health care needs. We believe that having MOOP and cost sharing standards that are predictable and stable from 1 year to the next supports this goal. To ensure that this goal is met in connection with the cost sharing polices as well, we must also take into account the change from the current (contract years 2021 and 2022) cost sharing limits, particularly copayment limits, to cost sharing limits that will be set under this rule.

We developed our proposal to create reasonable differences (which took into consideration the effect of the \$5 increment rounding proposal for professional service categories) in the cost sharing permitted for different types of MOOP limit in order to create meaningful incentives for MA organizations to offer plans with lower MOOP limits. However, some of the contract year 2022 copayment limits have been in place for a number of years and were set to prohibit discriminatory cost sharing by striking a balance between limiting beneficiary out-of-pocket costs and the potential impact to plan design and costs, with the goal of

ensuring beneficiary access to affordable and sustainable benefit packages. In the February 2020 proposed rule, we noted that we chose to assign actuarially equivalent copayments to 30 percent coinsurance for MA plans that establish a mandatory MOOP limit in order to be closer to the limits in the CY 2020 Call Letter for professional services. While MA plans (regardless of the type of MOOP limit) could have established a coinsurance up to 50 percent for professional services in contract year 2020, the copayment limits for the same professional service categories were approximately equal to 30 percent coinsurance for several of the professional service categories (based on the Medicare FFS data projections available at the time of the February 2020 proposed rule). As a result, while our proposal was designed to keep some copayment limits aligned with prior years by using a copayment limit that would be actuarially equivalent to 30 percent coinsurance, changing the coinsurance limit from 50 percent to 30 percent in one year represented a more significant change for MA plans that establish a mandatory MOOP limit. While MA plans may consider establishing lower MOOP limits based on the cost sharing flexibilities (which maintain a 50 percent coinsurance limit from prior years), we recognize that most plans currently utilize a mandatory MOOP limit and organizations may need time to modify provider contracts and their plan designs to accommodate a lower MOOP limit or a 20 percent increase in MA plan financial liability across several professional service categories.

Our proposed methodology to calculate copayment limits based on coinsurance percentages that are unique to the plan's MOOP limit type and the most recent Medicare FFS data projections available was, in effect, a proposal to recalibrate and update current copayment limits, using a methodology based on long-standing CMS policy with some changes. As a result, some of the illustrative copayment limits in Table 5 (Illustrative Contract Year 2022 In-Network Service Category Cost Sharing Limits) from the February 2020 proposed rule represented substantial shifts from the 2020 and 2021 contract years. For example, as referenced by some commenters, the illustrative \$85 copayment limit in the February 2020 proposed rule for the "physical therapy and speech-language pathology" service category (for MA plans that establish

a mandatory MOOP limit) represented an increase of \$45 from the contract year 2021 copayment limit for that service category. Similarly, the illustrative \$80 copayment limit for the "physician specialist" service category in the February 2020 proposed rule (for MA plans that establish a lower MOOP limit) reflected an increase of \$50 from the copayment limit established for 2021. These illustrative copayment limits (and the updated actuarially equivalent copayment values in Tables 14A, 14B, and 15) show how some of the copayment limits from contract year 2022 represent a significantly lower actuarially equivalent value than 50 percent coinsurance based on more recent Medicare FFS data projections. Despite the increases, CMS expects annually updating, based on the most recent Medicare FFS data projections, these long-standing copayment limits to values that are actuarially equivalent to coinsurance percentages will be an improvement from prior years. If CMS maintained copayment limits at lower amounts, MA organizations would still be able to establish higher cost sharing using coinsurance structures. Adopting requirements where the cost sharing limits are more equalized for coinsurance and copayment structures will provide transparency and more uniformity into the actual costs beneficiaries may experience.

We expect updating copayment limits to align with coinsurance limits based on the most recent Medicare FFS data projections will encourage the use of copayments in MA plan designs. We anticipate that MA organizations may take advantage of the increased flexibility for copayments resulting from this FC when establishing cost sharing for these service categories in future years. As stated in Chapter 4 of the MMCM, enrollees generally find copayment amounts more predictable and less confusing than coinsurance³⁸. This is the case because copayments are defined amounts while coinsurance may have a unique cost sharing amount based on the particular provider and the amount that provider has negotiated with the MA plan as payment.

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³⁸ Loewenstein G, Friedman JY, McGill B, Ahmad S, Linck S, Sinkula S, Beshears J, J.Choi J, Kolstad J, Laibson D, Madrian BC, List JA, Volpp KG. "Consumers' misunderstanding of health insurance". Journal of Health Economics 2013;32(5):850-862. Retrieved from: https://scholar.harvard.edu/laibson/publications/consumers-misunderstanding-health-insurance

Specifically, beneficiaries can more easily predict potential out-of-pocket costs for their expected health care needs over the year before receiving the services if copayment designs are used. If coinsurance designs are used, beneficiaries cannot make as accurate predictions until the unique cost sharing amount for the providers and services they expect to utilize are known. Therefore, changes that encourage the use of copayments may support beneficiaries in understanding their expected out of pocket costs in MA plans. We recognize that MA organizations may need time to modify provider contracts and prepare for implementing a copayment structure if they have previously used coinsurance structures in their plan designs. Updating the copayment limits to reflect the most recently developed actuarially equivalent values will also address the advances in medical technology utilized by the professional specialties, the costs MA organizations are expected to incur in providing these services for MA enrollees, and appropriate adjustments for medical inflation since the current copayment limits were last set. The cost sharing limits set in contract year 2022 have been in place for a number of years, so we are cognizant that an immediate change to the coinsurance and copayment limits established in this FC could be disruptive for some service categories if there is not a transition period. But we still expect that a transition to actuarially equivalent values for copayment limits, calculated at the coinsurance percentages that provide a meaningful differentiation between the types of MOOP limits, will ultimately result in stable benefit packages by ensuring cost sharing limits are calculated following established actuarial methods, using the most recent Medicare FFS data projections available, and by keeping copayment limits aligned with coinsurance limits.

In an effort to minimize the risk of disruptive changes and be responsive to commenters' concerns, we are finalizing a process to transition from current practice to the range of coinsurance and actuarially equivalent copayment limits based on the type of MOOP limit proposed in § 422.100(f)(6)(iii). We expect that a multiyear implementation schedule could be helpful to: (1) mitigate potentially disruptive changes based on the substantial projected increases to certain service category copayment limits resulting from using recent Medicare FFS data

projections; and (2) be responsive to commenter requests to provide time for MA organizations and enrollees to adjust to updated cost sharing limits. We thank the commenter for providing the example (reproduced in Table 12) of how CMS could conduct a multiyear phase in to implement a range of cost sharing standards by the type of MOOP limit for professional services. We believe this recommendation effectively addresses the concerns to provide time for MA organizations and enrollees to adjust to updated coinsurance limits, with edits based on the timing of this FC and to remain consistent with our rounding proposal in paragraph (f)(6)(ii). Specifically, in the commenter's example the intermediate MOOP limit equaled 47.5 percent and 42.5 percent for contract years 2022 and 2024. As we proposed general rules to govern how CMS rounds down to the lower dollar amount in cases where the copayment limit is projected to be exactly between two increments in paragraph (f)(6)(ii)(B), we believe applying this methodology to the coinsurance limits (that are applied to the same service categories as those rounded copayment limits) is appropriate to continue protecting enrollees from higher costs by rounding down whenever possible. We also believe whole percentages would be more easily understood by beneficiaries and implemented by MA plans that use coinsurance structures. In addition, incorporating decimal point differences would necessitate changes to the existing PBP software while applying the rounding rules avoids such modifications. Further, CMS is delaying applicability of this provision to begin for contract year 2023 as discussed previously in section II.B.5. of this FC based on the timing of this FC, so we are not adopting the commenter's specific recommendation as reflected in Table 12. CMS is adopting a multiyear transition similar to the commenter's recommendation, to transition coinsurance limits from the prior 50 percent coinsurance standard. The transition schedule we are finalizing in § 422.100(f)(6)(iii) is in Table 13, which includes the coinsurance limits used for contract year 2022 to provide context.

TABLE 13: FINAL MULTIYEAR PHASE-IN FOR COINSURANCE LIMTS BASED ON THE MOOP TYPE FOR SERVICE CATEGORIES SUBJECT TO § 422.100(f)(6)(iii)

MOOP Type	2022	2023	2024	2025	2026 and Future
					Years

Lower (Previously "voluntary")	50%	50%	50%	50%	50%
Intermediate	N/A	47%	45%	42%	40%
Mandatory	50%	45%	40%	35%	30%

To implement the multiyear transition in Table 13 to the proposed coinsurance limits, CMS is finalizing additional paragraphs at § 422.100(f)(6)(iii)(D) – (F). The substance of what was proposed at paragraph (f)(6)(iii)(C) is being finalized at paragraph (f)(6)(iii)(F) to govern the cost sharing that is permitted for MA plans using the different MOOP types beginning with coverage in 2026. Specifically, for contract year 2023, as finalized at paragraph (f)(6)(iii)(C), MA plans must not exceed the cost sharing limits for professional service categories as follows:

- Mandatory MOOP limit: 45 percent coinsurance or an actuarially equivalent copayment value and the MA plan must not pay less than 55 percent of the estimated total MA plan financial liability for the benefit.
- Intermediate MOOP limit: 47 percent coinsurance or an actuarially equivalent copayment value and the MA plan must not pay less than 53 percent of the estimated total MA plan financial liability for the benefit.
- Lower MOOP limit: 50 percent coinsurance or an actuarially equivalent copayment value and the MA plan must not pay less than 50 percent of the estimated total MA plan financial liability.

As finalized, § 422.100(f)(6)(iii)(B) directs how copayment limits calculated by CMS take precedence over amounts MA organizations may calculate and applies to paragraphs (f)(6)(iii)(C) – (F). In addition, paragraph (f)(6)(iii)(C) no longer references paragraph (f)(6)(ii)(A) to reduce repetitive references to the rounding rules. All of the rounding rules under paragraph (f)(6)(ii) are applicable to the copayments calculated under paragraph (f)(6)(iii). Paragraphs (f)(6)(iii)(D) through (F) reflect the transition after contract year 2023, as included in Table 13.

Although this transition schedule we are finalizing in § 422.100(f)(6)(iii)(C) through (F) addresses our concerns about sudden changes to the permitted level of coinsurance, it does not fully address our concerns about how the majority of copayment limits for professional service categories that apply for contract year 2022 (which are similar if not the same as copayment limits in earlier years) are roughly an actuarial equivalent value to, or less than, 30 percent coinsurance (as discussed previously in this response). We believe additional steps are necessary to smooth the transition from the copayment limits announced for contract year 2022 for MA plans that use copayment structures instead of coinsurance. For example, the contract year 2022 copayment limit for the "primary care physician" service category was \$35 (for both the voluntary and mandatory MOOP limits) and calculating copayment limits at actuarially equivalent values to 45, 47, and 50 percent for contract year 2023 (using contract year 2023) Medicare FFS data projections based on 2017 to 2021 Medicare FFS data), would increase the copayment limits to \$50, \$55, and \$60 for the mandatory, intermediate, and lower MOOP limits, respectively. Then, in applying the coinsurance percentages finalized for contract 2026, our projections show the limits would decrease over the subsequent years to \$35, \$45, and \$60 (the \$35 and \$45 amounts are the same as the illustrative copayment limits for this service category in Table 5: "Illustrative Contract Year 2022 In-Network Service Category Cost Sharing Limits" in the February 2020 proposed rule, while the illustrative copayment for the lower MOOP type was \$55 based on 2015 – 2019 Medicare FFS data projections). This is because, as we discussed previously, contract year 2022 copayment limits for most professional service categories do not reflect actuarially equivalent dollar amounts to 50 percent coinsurance that are calculated using contract year 2023 Medicare FFS data projections (based on 2017 – 2021 Medicare FFS data). In comparison, the separate methodology we are finalizing in paragraph (f)(8) to transition copayment limits does not produce this type of fluctuation. For example, using the methodology in paragraph (f)(8) results in final contract year 2023 primary care copayment limits of \$35, \$40, and \$40 for the mandatory, intermediate, and lower MOOP limits, respectively (as shown in

Table 28). We prevent potentially disruptive changes to copayment limits during the transition of coinsurance limits if we use a separate transition for copayment limits. We next address new paragraph (f)(8) and the final rule policy to apply additional steps to transition the copayment limits that are subject to paragraph (f)(6)(iii).

New § 422.100(f)(8) provides a multiyear transition for how CMS will change copayment limits from their current (contract year 2022) level to actuarially equivalent values for service categories subject to paragraph (f)(6)(iii) (and § 422.100(j)(1) as discussed in section II.B.5.e. of this FC). This transition will also be conducted over contract years 2023 through 2025, and result in CMS calculating, for contract year 2026 and subsequent years, copayment limits using actuarial equivalent values to the coinsurance percentages proposed for each MOOP type. However, this transition for (and cap on increases for) copayment limits in paragraph (f)(8) will not apply to the service categories subject to paragraph (f)(6)(i) and (f)(6)(iv). We proposed separate approaches for calculating the cost sharing limits for the services addressed in paragraph (f)(6)(i) and (f)(6)(iv). For contract year 2023, CMS calculated copayment limits for two service categories included in the PBP that are subject to paragraph (f)(6)(i) based on a review of the contract year 2023 Medicare FFS data projections and consultation with the OACT. These two service categories are the "DME – Diabetic Shoes or Inserts" and "DME – Diabetes Monitoring Supplies" service categories (for the lower MOOP type). Because CMS has not previously issued copayment limits for these service categories for MA plans that establish a lower MOOP limit, a copayment transition is not necessary for the "DME – Diabetic Shoes or Inserts" or the "DME – Diabetes Monitoring Supplies" service categories or for the other service categories subject to paragraph (f)(6)(i) that did not have a specific copayment limit for contract year 2022. Our final policy for the service categories subject to paragraph (f)(6)(i) and (f)(6)(iv) is more comprehensively addressed in sections II.B.5.a. and c. of this FC. For contract year 2026 and subsequent years, when CMS calculates copayment limits for in-network professional services

that are basic benefits, it will do so using the methodology in paragraphs (f)(6)(iii), (f)(7), and (j)(1) but not paragraph (f)(8).

Section 422.100(f)(8) limits the amount of annual increase in copayment limits for a service category subject to § 422.100(f)(6)(iii) or (j)(1) during the transition. Specifically, paragraph (f)(8) requires CMS to set these copayment limits at an amount that is the lesser of: (1) an actuarially equivalent value to the applicable cost sharing standard (from paragraph (f)(6)(iii) or (i)(1); or (2) the value resulting from the actuarially equivalent copayment transition in paragraph (f)(8)(ii) for that service category. In addition, these copayment limits are all rounded as provided in paragraph (f)(6)(ii). The copayment limits calculated using the formula in paragraph (f)(8)(ii) act as a cap on the copayment limits CMS sets following the requirements in paragraph (f)(6)(iii)(C) through (E). By "cap" here and in the regulation text, we mean that increases to the copayment limit will be governed by the formula in paragraph (f)(8)(ii). For example, if the value that is actuarially equivalent to 40 percent coinsurance (the coinsurance limit applicable for contract year 2024 for the mandatory MOOP type) for a given professional service category is \$100 when applying paragraph (f)(6)(iii)(D)(1) and the value is \$75 when applying the formula in paragraph (f)(8)(ii), then the copayment limit set by CMS for that professional service in 2024 for MA plans that establish a mandatory MOOP amount is \$75. In applying paragraphs (f)(6)(iii) and (f)(8), coinsurance and copayment limits are simultaneously transitioned to reach the proposed cost sharing limits by contract year 2026. As a result, the cost sharing limits (coinsurance and copayments) will be equalized (or actuarially equivalent to one another) by contract year 2026.

Section 422.100(f)(8)(i) defines the main component of the formula used in paragraph (f)(8)(ii) for this transition of copayment limits: the actuarially equivalent copayment differential. The methodology under paragraph (f)(8)(ii) occurs over 4 years (beginning for contract year 2023) and is structured in a similar manner as proposed (and finalized) for ESRD costs (as discussed in sections II.A. and II.B.5.c. of this FC). Similar to the ESRD cost transition,

this actuarially equivalent copayment transition factors in an increasing percentage of the difference between two values. The "actuarially equivalent copayment differential" is defined in paragraph (f)(8)(i) as:

- For cost sharing at the mandatory and lower MOOP limits, the difference between, first, the copayment limit set for a plan benefit package service category based on the MOOP type for 2022 and second, the projected actuarially equivalent copayment value for the same service category and MOOP type based on the coinsurance limits in §§ 422.100(f)(6)(iii) and (j)(1) that apply in 2026.
- For cost sharing at the intermediate MOOP limit, the difference between, first, the copayment limit set for a plan benefit package service category based on the mandatory MOOP type for 2022 and second, the projected actuarially equivalent copayment value for the same service category based on the coinsurance limits in §§ 422.100(f)(6)(iii) and (j)(1) that apply for the intermediate MOOP type in 2026.

Given the limited number of professional service categories in contract year 2022 that had cost sharing limits differentiated by the type of MOOP limit, the first value (for most comparisons) will be based on the same figure for each professional service category for which CMS may calculate copayment limits during the transition. The second value (the actuarially equivalent copayment to the applicable cost sharing standard) will be recalculated each year using updated Medicare FFS data projections, consistent with the standards in paragraph (f)(7). This definition of the "actuarially equivalent copayment differential" means that each year, for each service category subject to paragraph (f)(6)(iii) to which paragraph (f)(8)(i) applies, CMS will calculate the difference between these two figures for each service category:

• For the mandatory MOOP limit: the copayment limit set for contract year 2022 for the mandatory MOOP limit and the copayment value that is actuarially equivalent to 30 percent (the coinsurance limit that applies in 2026) using the Medicare FFS data projections (updated each year) to reflect the costs of the contract year for which the copayment limit will apply.

- For the intermediate MOOP limit: the copayment limit set for contract year 2022 for the mandatory MOOP limit and the copayment value that is actuarially equivalent to 40 percent (the coinsurance limit that applies in 2026) using the Medicare FFS data projections (updated each year) to reflect the costs of the contract year for which the copayment limit will apply.
- For the lower MOOP limit: the copayment limit set for contract year 2022 for the voluntary MOOP limit and the copayment value that is actuarially equivalent to 50 percent (the coinsurance limit that applies in 2026) using the Medicare FFS data projections (updated each year) to reflect the costs of the contract year for which the copayment limit will apply.

 In comparison, the "actuarially equivalent copayment differential" as defined and applied to service categories subject to § 422.100(j)(1) (as discussed in section II.B.5.e. of this FC) means that CMS will calculate, for all MOOP limits (unless otherwise specified in paragraph (j)(1)(i)), the difference between these two figures for each service category: (1) the copayment limit set for contract year 2022 and (2) the copayment value that is actuarially equivalent to cost sharing under original Medicare that applies in 2026 using the Medicare FFS data projections (updated each year) to reflect the costs of the contract year for which the copayment limit will apply.

 Assuming that there are no changes to cost sharing rules in original Medicare, this second figure will be an actuarially equivalent value to 20 percent coinsurance for most of the services listed in § 422.100(j)(1).

As a result, the value of the "actuarially equivalent copayment differential" is unique for each service category, MOOP type, and contract year. Tables 14A, 14B, and 15 illustrate how the actuarially equivalent copayment differential is calculated in row H in each table.

Section 422.100(f)(8)(ii) provides the specific formula CMS will follow to complete the actuarially equivalent copayment transition. Specifically, CMS will add a percentage of the "actuarially equivalent copayment differential" identified for each service category, MOOP type, and contract year to the copayment limit set for contract year 2022 for that service category. The

percentage of the actuarially equivalent copayment differential that will be used each year is as follows:

- Contract Year 2023: 25 percent.
- Contract Year 2024: 50 percent.
- Contract Year 2025: 75 percent.

This means that for each year and service category subject to § 422.100(f)(6)(iii) or (j)(1) to which (f)(8)(ii) applies, CMS will calculate the transitional value under paragraph (f)(8) that will be compared to what is actuarially equivalent to the applicable coinsurance limit for that contract year to determine which is the lesser value. Each year, CMS will use the most recent Medicare FFS data projections for the contract year to calculate these figures. Specifically, for contract year 2023, the formula to calculate the transitional value is as follows:

- For the mandatory and lower MOOP limits: the respective copayment limits set for 2022 plus 25 percent of the actuarially equivalent copayment differential.
- For the intermediate MOOP limit: the copayment limits set for 2022 for the mandatory MOOP limit plus 25 percent of the actuarially equivalent copayment differential.

By capping the copayment limits to the "lesser of" value for years 2023 through 2025, we aim to smooth the transition from the current (contract year 2022) copayment limits to the copayment limits that will be based on the coinsurance levels permitted for each type of MOOP limit. The transition adopted at § 422.100(f)(8) applies only to copayment limits that were set for contract year 2022. If CMS calculates a copayment limit for a new service category (where a copayment limit was not set for contract year 2022) that would be subject to either § 422.100(f)(6)(iii) or (j)(1) during this transition period, those copayment limits for those new service categories would be calculated at a value that is actuarially equivalent to the coinsurance percentage for the applicable MOOP limit under the rules in paragraphs (f)(6)(iii) and (j)(i).

As referenced in section II.B.5.a. of this FC, CMS may calculate copayment limits for any category of professional services that are basic benefits for 2023 and future years. Our

intention is to calculate copayment limits for as many service categories as possible that are subject to $\S 422.100(f)(6)(i)$, (iii), and (j)(1). In this FC, we apply $\S 422.100(f)(6)(iii)$ to calculate final contract year 2023 copayment limits for the same professional service categories for which CMS set copayment limits in contract year 2022. Tables 14A and 14B show the calculations of contract year 2023 copayment limits for several professional services categories for MA plans that establish a mandatory MOOP type; CMS used contract year 2023 Medicare FFS data projections (based on 2017 – 2021 Medicare FFS data) to develop these tables. Calculations similar to those shown in Tables 14A and 14B was used to reach the final contract year 2023 copayment limits included in Table 28 for MA plans that establish a lower or intermediate MOOP type. As an example, calculations of the contract year 2023 copayment limits for the "cardiac rehabilitation" service category for all MOOP types is provided in Table 15. The calculation of a contract year 2023 copayment limit for the "Part B drugs – Other" service category is not included in Table 14A or 14B, as CMS is not finalizing a range of coinsurance limits based on the type of MOOP limit for this service category, as discussed in section II.B.5.e. of this FC.

Tables 14A and 14B illustrate how CMS applies the methodology in § 422.100(f)(8) to calculate transitional copayment limits for service categories subject to paragraph (f)(6)(iii) for contract year 2023. The total projected Medicare FFS cost for each service category in Tables 14A, 14B, and 15 is based solely on Medicare FFS data (MA encounter data for the same time period was unavailable at the time of writing this FC). In addition, the total projected Medicare FFS cost reflects the lesser value (that is, when a median and weighted average amount were compared, we selected the lesser value) for the service categories in Tables 14A, 14B, and 15 except for "urgently needed services". The total projected Medicare FFS weighted average and median amounts for "urgently needed services" for contract year 2023 are \$134.00 and \$113.00, respectively. The standard finalized in paragraph (f)(7)(ii)(C) authorizes CMS to select among different approaches to avoid unnecessary fluctuations in the copayment limit, so we choose to

use the higher amount (\$134.00) as the contract year 2023 total Medicare FFS projected cost for this service category. Specifically, using the higher \$134.00 weighted average to calculate contract year 2023 copayment limits for the "urgently needed services" service category decreases the amount of change from the contract year 2022 copayment limit (\$65 for both MOOP types) in comparison to the transitional copayment limits that would result from using the \$113.00 median value.

As shown in Tables 14A, 14B, and 15, CMS calculated an actuarially equivalent copayment to the coinsurance limit applicable for contract year 2023 (45 percent for the mandatory MOOP limit, per paragraph (f)(6)(iii)(C)) for each service category by using the total projected Medicare FFS cost (in row B from Tables 14A, 14B, and 15). CMS calculated the transitional copayment value using the methodology finalized in paragraph (f)(8)(ii). As shown in Tables 14A and 14B, we calculated the actuarially equivalent copayment value based on 30 percent coinsurance of the total projected Medicare FFS cost (that is, the coinsurance limit for contract year 2026 for the mandatory MOOP limit, per paragraph (c)(6)(iii)(F)) and compared that value to the contract year 2022 copayment limit for the same service category and MOOP limit to reach the "actuarially equivalent copayment differential". Then, we took 25 percent of the "actuarially equivalent copayment differential" and added it to the contract year 2022 copayment amount and applied the rounding rules in paragraph (f)(6)(ii) to reach the transitional contract year 2023 copayment value for that service category and MOOP type (the values in row K in Tables 14A and 14B). Then, we compared the transitional copayment values (calculated following paragraph (f)(8)(ii)) to the actuarially equivalent value of the applicable cost sharing standard for contract year 2023 (calculated following paragraph (f)(6)(iii)(C)). The lesser value between these two amounts is included in row L of Tables 14A and 14B as the contract year 2023 copayment limit for that service category and MOOP type.

For example, as shown in Table 14B, the contract year 2022 "primary care physician" service category copayment limit for MA plans that established a mandatory or voluntary (lower)

MOOP amount was \$35. Using contract year 2023 Medicare FFS data projections (based on 2017 – 2021 Medicare FFS data), a \$35 copayment is actuarially equivalent to 30 percent coinsurance. In essence, this means that the final contract year 2023 copayment limit for the "primary care physician" service category and mandatory MOOP type reflects an actuarially equivalent copayment to the 2026 standard for that MOOP type in paragraph (f)(6)(iii)(F). In comparison, the copayment limit for this service category and the lower MOOP type is a transitional value, and not fully actuarially equivalent to the 2026 standard for that MOOP type (increasing from \$35 for contract year 2022 to \$40 for contract year 2023 as shown in Table 28). As a result, the multiyear transition in paragraph (f)(8) for CMS to calculate actuarially equivalent copayment limits avoids unnecessary changes to the copayment limits from year to year.

The "lesser of" values in row L of Tables 14A, 14B, and 15 are in Table 28 as the final contract year 2023 copayment limits for the respective MOOP types. Table 28 updates the illustrative cost sharing limits for all three MOOP types from the February 2020 proposed rule's Table 5 (Illustrative Contract Year 2022 In-Network Service Category Cost Sharing Limits), using contract year 2023 Medicare FFS data projections (based on 2017 – 2021 Medicare FFS data) and applying the requirements finalized in paragraphs (f)(6), (7), (8), and § 422.100(j)(1). As a result, the final contract year 2023 copayment limits in Table 28 are consistent with how paragraph (f)(8) provides that the lesser of values calculated under paragraphs (f)(6)(iii) and (i)(1) and values calculated under paragraph (f)(8) will be used as the copayment limit for a particular service category and cost sharing level. In addition, Table 28 includes final contract year 2023 copayment limits for several service categories that did not have illustrative copayment limits in the February 2020 proposed rule. Final contract year 2023 copayment limits for the following professional service categories are in Table 28 but were not illustrated in the similar table in the February 2020 proposed rule: cardiac rehabilitation; intensive cardiac rehabilitation; pulmonary rehabilitation; Supervised exercise therapy (SET) for Symptomatic

peripheral artery disease (PAD); and partial hospitalization. These are all professional services subject to the methodology finalized in § 422.100(f)(6)(iii), (f)(7), and (f)(8). This is consistent with the general approach we proposed that the same rules would apply for all professional services if CMS issues copayment limits, regardless of whether we had calculated a copayment limit for the category in the past. By following the "lesser of" requirement in paragraph (f)(8), choosing the measure of central tendency which produces the least amount of change from the prior contract year (as allowed in paragraph (f)(7)) when calculating actuarially equivalent values, and setting copayment limits for the service categories we have historically used for contract year 2023, we aim to avoid potentially disruptive copayment changes, such as copayment limits that fluctuate up and down over short periods of time, for enrollees and plan designs.

Tables 14A, 14B, and 15 also illustrate how CMS will generally approach applying the methodology in § 422.100(f)(8) for service categories subject to paragraph (f)(6)(iii) for contract years 2024 and 2025. Specifically, CMS will complete similar calculations of the copayment limits for contract years 2024 and 2025 as shown in Tables 14A, 14B, and 15 with modifications to reflect the specific coinsurance limits for each year, increases in the actuarial equivalent copayment differential used (per paragraph (f)(8)), and updates to the total Medicare FFS costs for each service category using the most recent Medicare FFS data projections.

TABLE 14A: CMS CALCULATIONS OF THE CONTRACT YEAR 2023 ACTUARIALLY EQUIVALENT COPAYMENT TRANSITION (§ 422.100(f)(8)) FOR SERVICE CATEGORIES IN PBP SECTIONS 3, 4b, AND 5 SUBJECT TO § 422.100(f)(6)(iii) FOR THE MANDATORY MOOP TYPE USING CONTRACT YEAR 2023 MEDICARE FFS DATA PROJECTIONS (BASED ON 2017 – 2021 MEDICARE FFS DATA)

Row		Intensive Cardiac	Pulmonary		Urgently	Partial
Reference	Description	Rehabilitation	Rehabilitation	SET for PAD	Needed Services	Hospitalization
A	Contract year 2022 copayment limit	\$100.00	\$30.00	\$30.00	\$65.00	\$55.00
В	Contract year 2023 total Medicare FFS projected cost ¹	\$132.002	$$39.00^2$	\$65.00 ²	\$134.003	\$275.004
С	Contract year 2023 coinsurance limit per § 422.100(f)(6)(iii)(C)(1)	45%	45%	45%	45%	45%
D	Unrounded actuarially equivalent copayment value to contract year 2023 coinsurance limit per § 422.100(f)(6)(iii)(C) (row B multiplied by row C)	\$59.40	\$17.55	\$29.25	\$60.30	\$123.75
Е	Rounded actuarially equivalent copayment value to contract year 2023 coinsurance limit per § 422.100(f)(6)(iii)(C) (row D rounded per § 422.100(f)(6)(ii))	\$60.00	\$20.00	\$30.00	\$60.00	\$125.00
F	Contract year 2026 coinsurance limit per § 422.100(f)(6)(iii)(F)(1)	30%	30%	30%	30%	30%
G	Unrounded actuarially equivalent copayment value to contract year 2026 coinsurance limit per § 422.100(f)(6)(iii)(F) (row B multiplied by row F)	\$39.60	\$11.70	\$19.50	\$40.20	\$82.50
Н	Actuarially Equivalent Copayment Differential per § 422.100(f)(8)(i) (difference between row G and row A)	(\$60.40)	(\$18.30)	(\$10.50)	(\$24.80)	\$27.50
I	25% of the Actuarially Equivalent Copayment Differential per § 422.100(f)(8)(ii)(A) (row H multiplied by 0.25)	(\$15.10)	(\$4.58)	(\$2.63)	(\$6.20)	\$6.88
J	Unrounded copayment value result from actuarially equivalent copayment transition formula for contract year 2023 per § 422.100(f)(8)(ii)(A) (row A plus row I)	\$84.90	\$25.43	\$27.38	\$58.80	\$61.88
K	Rounded copayment value result from actuarially equivalent copayment transition formula for contract year 2023 per § 422.100(f)(8)(ii)(A) (row J rounded per § 422.100(f)(6)(ii))	\$85.00	\$25.00	\$25.00	\$60.00	\$60.00
L	Contract year 2023 "lesser of" copayment value per § 422.100(f)(8) (the lesser value of row E and row K)	\$60.00	\$20.00	\$25.00	\$60.00	\$60.00

¹The OACT employed generally accepted actuarial principles and practices in calculating these projected amounts (as finalized in § 422.100(f)(7).

²These amounts represent the total projected Medicare FFS average per session allowed amount for the service category in contract year 2023, weighted by the type of setting (such as, hospital outpatient departments and provider offices).

³This amount for the "urgently needed services" service category represents the total projected Medicare FFS weighted average per visit allowed amount for contract year 2023.

⁴This amount for the "partial hospitalization" service category represents the total projected Medicare FFS average per day allowed amount, weighted by the type of setting (such as, hospital outpatient departments and community mental health centers).

TABLE 14B: CMS CALCULATIONS OF THE CONTRACT YEAR 2023 ACTUARIALLY EQUIVALENT COPAYMENT TRANSITION (§ 422.100(f)(8)) FOR SERVICE CATEGORIES IN PBP SECTIONS 7a – 7e and 7h-7i SUBJECT TO § 422.100(f)(6)(iii) FOR THE MANDATORY MOOP TYPE USING CONTRACT YEAR 2023 MEDICARE FFS DATA PROJECTIONS (BASED ON 2017 – 2021 MEDICARE FFS DATA)

Row Reference	Description	Primary Care Physician	Chiropractic Care	Occupational Therapy	Physician Specialist	Mental Health Specialty Services	Psychiatric Services	Physical Therapy and Speech- language Pathology
A	Contract year 2022 copayment limit	\$35.00	\$20.00	\$40.00	\$50.00	\$40.001	\$40.001	\$40.00
В	Contract year 2023 total Medicare FFS projected cost ²	\$115.91	\$52.00	\$125.00	\$179.64	\$153.30	\$145.00	\$178.96
С	Contract year 2023 coinsurance limit per § 422.100(f)(6)(iii)(C)(<i>I</i>)	45%	45%	45%	45%	45%	45%	45%
D	Unrounded actuarially equivalent copayment value to contract year 2023 coinsurance limit per § 422.100(f)(6)(iii)(C) (row B multiplied by row C)	\$52.16	\$23.40	\$56.25	\$80.84	\$68.99	\$65.25	\$80.53
Е	Rounded actuarially equivalent copayment value to contract year 2023 coinsurance limit per § 422.100(f)(6)(iii)(C) (row D rounded per § 422.100(f)(6)(ii))	\$50.00	\$25.00	\$55.00	\$80.00	\$70.00	\$65.00	\$80.00
F	Contract year 2026 coinsurance limit per § 422.100(f)(6)(iii)(F)(I)	30%	30%	30%	30%	30%	30%	30%
G	Unrounded actuarially equivalent copayment value to contract year 2026 coinsurance limit per § 422.100(f)(6)(iii)(F) (row B multiplied by row F)	\$34.77	\$15.60	\$37.50	\$53.89	\$45.99	\$43.50	\$53.69
Н	Actuarially Equivalent Copayment Differential per § 422.100(f)(8)(i) (difference between row G and row A)	(\$0.23)	(\$4.40)	(\$2.50)	\$3.89	\$5.99	\$3.50	\$13.69
I	25% of the Actuarially Equivalent Copayment Differential per § 422.100(f)(8)(ii)(A) (row H multiplied by 0.25)	(\$0.06)	(\$1.10)	(\$0.63)	\$0.97	\$1.50	\$0.88	\$3.42
J	Unrounded copayment value result from actuarially equivalent copayment transition formula for contract year 2023 per § 422.100(f)(8)(ii)(A) (row A plus row I)	\$34.94	\$18.90	\$39.38	\$50.97	\$41.50	\$40.88	\$43.42

Row Reference	Description	Primary Care Physician	Chiropractic Care	Occupational Therapy	Physician Specialist	Mental Health Specialty Services	Psychiatric Services	Physical Therapy and Speech- language Pathology
K	Rounded copayment value result from actuarially equivalent copayment transition formula for contract year 2023 per § 422.100(f)(8)(ii)(A) (row J rounded per § 422.100(f)(6)(ii))	\$35.00	\$20.00	\$40.00	\$50.00	\$40.00	\$40.00	\$45.00
L	Contract year 2023 "lesser of" copayment value per § 422.100(f)(8) (the lesser value of row E and row K) ³	\$35.00	\$20.00	\$40.00	\$50.00	\$40.00	\$40.00	\$45.00

¹This amount reflects the copayment limit for the "psychiatric and mental health specialty services" service category as it was named for contract year 2022.

²Each amount represents the total average per visit Medicare FFS allowed amount for the service category, weighted by specialty type utilization (such as, family practice, general practice, internal medicine, and geriatric medicine for the primary care physician service category). The OACT employed generally accepted actuarial principles and practices in calculating these projected amounts (as finalized in § 422.100(f)(7)).

TABLE 15: CMS CALCULATIONS OF THE CONTRACT YEAR 2023 ACTUARIALLY EQUIVALENT COPAYMENT TRANSITION (§ 422.100(f)(8)) FOR THE CARDIAC REHABILITATION SERVICE CATEGORY (SUBJECT TO § 422.100(f)(6)(iii)) USING CONTRACT YEAR 2023 MEDICARE FFS DATA PROJECTIONS (BASED ON 2017 – 2021 MEDICARE FFS DATA)

Row		Mandatory MOOP	Intermediate MOOP	Lower MOOP
Reference	Description	Limit	Limit	Limit
A	Contract year 2022 copayment limit	\$50.00	N/A	\$50.00
В	Contract year 2023 total Medicare FFS projected cost		\$84.001	
С	Contract year 2023 coinsurance limit per § 422.100(f)(6)(iii)(C)	45%	47%	50%
D	Unrounded actuarially equivalent copayment value to contract year 2023 coinsurance limit per § 422.100(f)(6)(iii)(C) (row B multiplied by row C)	\$37.80	\$39.48	\$42.00
Е	Rounded actuarially equivalent copayment value to contract year 2023 coinsurance limit per § 422.100(f)(6)(iii)(C) (row D rounded per § 422.100(f)(6)(ii))	\$40.00	\$40.00	\$40.00
F	Contract year 2026 coinsurance limit per § 422.100(f)(6)(iii)(F)	30%	40%	50%
G	Unrounded actuarially equivalent copayment value to contract year 2026 coinsurance limit per § 422.100(f)(6)(iii)(F) (row B multiplied by row F)	\$25.20	\$33.60	\$42.00
Н	Actuarially Equivalent Copayment Differential per § 422.100(f)(8)(i) (difference between row G and row A)	(\$24.80)	$(\$16.40)^2$	(\$8.00)
I	25% of the Actuarially Equivalent Copayment Differential per § 422.100(f)(8)(ii)(A) (row H multiplied by 0.25)	(\$6.20)	(\$4.10)	(\$2.00)
J	Unrounded copayment value result from actuarially equivalent copayment transition formula for contract year 2023 per § 422.100(f)(8)(ii)(A) (row A plus row I)	\$43.80	\$45.902	\$48.00
K	Rounded copayment value result from actuarially equivalent copayment transition formula for contract year 2023 per § 422.100(f)(8)(ii)(A) (row J rounded per § 422.100(f)(6)(ii))	\$45.00	\$45.00	\$50.00
L	Contract year 2023 "lesser of" copayment value per § 422.100(f)(8) (the lesser value of row E and row K)	\$40.00	\$40.00	\$40.00

¹This amount represents the total average Medicare FFS per session allowed amount for the service category, weighted by the type of setting (such as, hospital outpatient departments and provider offices) for contract year 2023. The OACT employed generally accepted actuarial principles and practices in calculating this projected amount (as finalized in § 422.100(f)(7).

²For purposes of calculating these values for the intermediate MOOP limit, the comparison amount in row A for the mandatory MOOP limit is used per § 422.100(f)(8)(i)(B).

As shown in Tables 15 and 28, some contract year 2023 service category copayment limits are the same amount for multiple MOOP types (for example, a \$40 "cardiac rehabilitation" services" service category copayment limit for all MOOP types in contract year 2023). Some copayment limits are the same in the beginning of the transition because most professional categories have the same contract year 2022 copayment limit, along with the rounding rules. We do not expect the number of professional service categories with the same copayment limit will result in the number of MA plans with lower MOOP limits decreasing significantly because the cost sharing flexibilities generally provide differentiation for most service categories by MOOP type throughout the transition period. In addition, we currently project (based on contract year 2023 Medicare FFS data projections) that all service categories subject to paragraph (f)(6)(iii) will have differentiated copayment limits based on the MOOP type once the transition in paragraph (f)(8) is completed in contract year 2026. Under this FC, the OACT will annually update the Medicare FFS data projections used to calculate copayment limits, so the actual copayment limits for professional services for contract year 2024 and subsequent years, calculated by applying the rules in § 422.100(f)(6)(iii), (7), and (8), could increase or decrease accordingly.

As shown in Tables 14A, 15, and 28, the contract year 2023 copayment limits for the cardiac rehabilitation, intensive cardiac rehabilitation, and pulmonary rehabilitation service categories reflect decreases from the corresponding contract year 2022 copayment limits for both MOOP types. CMS calculated actuarially equivalent copayments for these service categories by using the contract year 2023 Medicare FFS data projections (based on 2017 - 2021 Medicare FFS data) of the total average per session cost (weighted by utilization of office and outpatient facilities). As a result, Medicare FFS data reflects changes in CMS payment policies, provider billing practices, and where services are provided (for example, hospital outpatient department or physician's office). In addition, the contract year 2023 copayment limits set for these service categories reflect application of the "lesser of" requirement in § 422.100(f)(8); the actuarially

equivalent value to the coinsurance limit for contract year 2023 is less than the value resulting from the actuarially equivalent copayment transition (after application of the rounding rules) for all MOOP types. The projected Medicare FFS amounts for cardiac rehabilitation and intensive cardiac rehabilitation also comply with Medicare FFS payment requirements from sections 1848(A)(5) and 1861(E) of the Act. These factors in combination result in the decreases in copayments limits for these three service categories from the contract year 2022 copayment limits.

As finalized in new § 422.100(f)(8)(ii)(D), the transition to actuarially equivalent copayment limits will be complete by contract year 2026 and no cap on increases in copayment limits apply for contract year 2026 or later years. For contract year 2026 and subsequent years, CMS may calculate copayment limits for--

- In-network professional services that are basic benefits: at an actuarially equivalent copayment value to the coinsurance percentage required for the type of MOOP limit, under paragraph (f)(6)(iii)(F); and
- In-network benefits subject to § 422.100(j)(1)(i): at actuarially equivalent values to the cost sharing under original Medicare (see additional discussion in section II.B.5.e. of this FC). In essence, we are finalizing a process of continuous recalibration of copayment limits for service categories subject to paragraph (f)(6)(iii) or (j)(1) to ensure those limits are appropriately updated to align with the coinsurance limits based on annually updated Medicare FFS data projections. This is consistent with our proposal to set the actuarially equivalent copayment values each year, by working with the OACT to establish copayment limits that are approximately equal to the identified coinsurance percentage limit based on the most recent Medicare FFS data projections.

Using contract year 2023 Medicare FFS data projections (based on 2017 – 2021 Medicare FFS data), applying § 422.100(f)(8), combined with the effect of applying the rounding rules, results in some service categories for particular MOOP types reaching an actuarially

equivalent copayment value before contract year 2026 while others are currently expected to take the full 4 years to reach a copayment limit that is an actuarially equivalent value to the applicable coinsurance requirement. Some of these potential outcomes for professional service categories are illustrated in Tables 16 and 17.

Table 16 illustrates how CMS would calculate the actuarially equivalent copayment transition (including the "lesser of" requirement) over the 4 years for the "SET for PAD" service category using contract year 2023 Medicare FFS data projections (based on 2017 – 2021 Medicare FFS data). (We reiterate that the transition provided in § 422.100(f)(8) only applies when: (1) CMS is calculating a copayment limit under paragraph (f)(6)(iii) for basic benefits that are professional services and § 422.100(j)(1) for basic benefits for which the cost sharing may not exceed cost sharing in original Medicare; and (2) there was a copayment limit published for contract year 2022 for that service category. When CMS does not calculate the copayment limit as a specific dollar amount, the MA plan would be in the position of calculating an actuarially equivalent value that the MA plan's copayments may not exceed.) For contract year 2022, the cost sharing limits for the "SET for PAD" service category are 50 percent coinsurance or a \$30 copayment for MA plans with the voluntary or mandatory MOOP type. As shown in Table 16, the mandatory MOOP limit is currently projected to reach an actuarially equivalent value based on 30 percent coinsurance in contract year 2025 for the "SET for PAD" service category, while the lower MOOP limit retains its copayment limit from contract year 2022 as that is the projected actuarially equivalent value to 50 percent coinsurance. Although the February 2020 proposed rule stated that 30 percent coinsurance is most closely related to the professional service category copayment limits from the CY 2020 Call Letter, that is not the case for every service category. For example, using contract year 2023 Medicare FFS data projections (based on 2017 – 2021 Medicare FFS data), the contract year 2022 copayment limits for the "urgently needed services" and "SET for PAD" service categories reflect an actuarially equivalent copayment value to 50 percent coinsurance. As a result, the lower MOOP type retains the contract year 2022 copayment

limit for the "urgently needed services" and "SET for PAD" service categories for contract year 2023 and the copayment limit for the mandatory MOOP type reflects a decrease from the contract year 2022 copayment limit in the first year of the transition to the lower coinsurance standard for that MOOP type. However, we emphasize that the copayment limits contained in Table 16 for contract years 2024 – 2026 are illustrative in nature and may change based on updated Medicare FFS data projections.

TABLE 16: FINAL CONTRACT YEAR 2023 AND ILLUSTRATIVE CONTRACT YEAR 2024 – 2026 COST SHARING LIMITS FOR THE "SET FOR PAD" SERVICE CATEGORY DURING THE MULTIYEAR TRANSITION (§ 422.100(f)(6)(iii) AND (f)(8)(i)) USING CONTRACT YEAR 2023 MEDICARE FFS DATA PROJECTIONS (BASED ON 2017 – 2021 MEDICARE FFS DATA)

MOOP Type	Contract Year 2022 ¹	Contract Year 2023 ²	Contract Year 2024 ³	Contract Year 2025 ³	Contract Year 2026 ³
Mandatory	50% / \$30	45% / \$25	40% / \$25	35% / \$204	30% / \$20
Intermediate	N/A	47% / \$30	45% / \$30	42% / \$255	40% / \$25
Lower (Previously "voluntary")	50% / \$30	50% / \$306	50% / \$30	50% / \$30	50% / \$30

¹Cost sharing limits for contract year 2022 provided for comparison purposes.

Table 17 illustrates how CMS will apply both the copayment and coinsurance transitions to the "physician specialist" service category through contract year 2026, using contract year 2023 Medicare FFS data projections (based on 2017 – 2021 Medicare FFS data). Cost projections for contract years after 2023 were not available at the time of writing this FC, however Table 17 illustrates the potential impact of the transition rule in calculating cost sharing limits for contract years 2024 through 2026. For example, Table 17 shows that in implementing a 4-year transition, an actuarially equivalent copayment limit to 30 percent coinsurance for the mandatory MOOP type may take the full 4 years to reach for the "physician specialist" service category. We reiterate that while the transition of the applicable coinsurance percentage and the rules for CMS to calculate the copayment limits are set in this FC, the copayment limits provided

²The contract year 2023 cost sharing limits are final and calculated using § 422.100(f)(6), (f)(7), and (f)(8).

³The copayment limits for these years are illustrative and final amounts will be announced using the subregulatory process at § 422.100(f)(7)(iii). The coinsurance limits for these years are final per § 422.100(f)(6)(iii).

⁴This is the projected year in which the copayment limit will reach an actuarially equivalent value to 30 percent coinsurance for the mandatory MOOP limit.

⁵ This is the projected year in which the copayment limit will reach an actuarially equivalent value to 40 percent coinsurance for the intermediate MOOP limit.

⁶ The contract year 2023 copayment limit for the lower MOOP limit reflects an actuarially equivalent value to 50 percent coinsurance.

in Tables 16 and 17 for contract years 2024 through 2026 are illustrative in nature and may change based on updated Medicare FFS data projections in future years. Tables 16 and 17 highlight how the transition schedules result in annual incremental changes in order to reach the cost sharing limits that we proposed by contract year 2026.

TABLE 17: FINAL CONTRACT YEAR 2023 AND ILLUSTRATIVE CONTRACT YEAR 2024 – 2026 COST SHARING LIMITS FOR THE "PHYSICIAN SPECIALIST" SERVICE CATEGORY DURING THE MULTIYEAR TRANSTION (§ 422.100(f)(6)(iii) AND (f)(8)(i)) USING CONTRACT YEAR 2023 MEDICARE FFS DATA PROJECTIONS (BASED ON 2017 – 2021 MEDICARE FFS DATA)

MOOP Type	Contract Year 2022 ¹	Contract Year 2023 ²	Contract Year 2024 ³	Contract Year 2025 ³	Contract Year 2026 ^{3,4}
Mandatory	50% / \$50	45% / \$50	40% / \$50	35% / \$55	30% / \$55
Intermediate	N/A	47% / \$55	45% / \$60	42% / \$65	40% / \$70
Lower (Previously "voluntary")	50% / \$50	50% / \$60	50% / \$70	50% / \$80	50% / \$90

¹Cost sharing limits for contract year 2022 provided for comparison purposes.

The multiyear transition schedule for copayment limits calculated by CMS will generally be applied consistently across professional services (including urgently needed services) and benefits for which cost sharing must not exceed cost sharing in original Medicare (as discussed previously in this response and in sections II.B.5.d. and e. of this FC) in order to streamline the methodology and preserve transparency as much as possible while meeting our goals of avoiding significant year-to-year changes in copayment limits. We expect the completion of the multiyear transition to the range of cost sharing limits proposed will: (1) improve the accuracy of copayment limits by using annually updated Medicare FFS data projections; (2) increase the flexibility MA organizations have in establishing copayments; (3) encourage the use of copayments and lower MOOP limits among MA plans; and (4) mitigate potential premium increases or benefit reductions if copayment limits did not accurately reflect projected costs.

In summary, we believe that using the multiyear transitions (for contract years 2023 through 2026) finalized in § 422.100(f)(6)(iii)(C) – (F) and (f)(8) provide sufficient time for MA organizations to address the upcoming changes to these cost sharing requirements; we do not expect this policy to directly cause plans to non-renew or to cause considerable disruption in the MA market or for beneficiaries. CMS requested comments and suggestions on its application and interpretation of the existing MOOP and cost sharing standards, as well as on adding a third, MOOP limit to allow additional cost sharing flexibility for future years, as part of the CY 2020

²The contract year 2023 cost sharing limits are final and calculated using § 422.100(f)(6), (f)(7), and (f)(8).

³The copayment limits for these years are illustrative and final amounts will be announced using the subregulatory process at § 422.100(f)(7)(iii). The coinsurance limits for these years are final per § 422.100(f)(6)(iii).

⁴ This is the projected year in which the copayment limits will reach actuarially equivalent values to the coinsurance standard that applies for 2026 for each MOOP type.

Call Letter³⁹ process. CMS took the suggestions received then into account when developing the February 2020 proposed rule. We therefore expect that these opportunities to comment on these concepts provided MA organizations and other stakeholders with additional time to anticipate and prepare for changes like those we are adopting here.

To provide additional transparency regarding how § 422.100(f)(6)(iii), (f)(7), and (f)(8) will be applied in future contract years, we provide an example of the steps CMS will take to calculate copayment limits for the "physician specialist" service category for contract year 2027 or a subsequent year. First, CMS will consider and decide whether issuing a copayment limit for the "physician specialist" service category is appropriate; we intend to review and consider the following using the most recent Medicare FFS data projections as part of this decision:

- The projected Medicare FFS costs and utilization for the relevant provider specialties for furnishing specialty physician services, such as average costs and utilization for the following provider specialties: cardiology, gastroenterology, nephrology, and otolaryngology (ENT); and
- Updated analyses of actuarially acceptable approaches to calculate an actuarially equivalent value to the applicable cost sharing standard in § 422.100(f)(6)(iii) from the OACT (for example, with or without waiting for utilization, or projected median total Medicare FFS allowed amounts or a Medicare FFS projected claims cost distribution).

As a result, some potential outcomes of applying paragraphs (f)(6)(iii)(F), (f)(7), and (f)(8)(ii)(D) to calculate copayment limits for the "physician specialist" service category for contract year 2027 may include the following:

• Maintaining the contract year 2026 copayment limits for contract year 2027 if the most recent Medicare FFS projections of the weighted average do not result in different actuarially equivalent values to the range of cost sharing standard (after application of the rounding rules in § 422.100(f)(6)(ii)).

 $^{^{39}}$ See pages 159-161 of the CY 2020 draft Call Letter at: https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2020Part2.pdf.

- Calculating updated copayment limits for contract year 2027 if the Medicare FFS data projections for the relevant provider specialties for furnishing specialty physician services result in different actuarially equivalent values to the range of cost sharing standard (after application of the rounding rules in § 422.100(f)(6)(ii)).
- Calculating updated copayment limits for contract year 2027 that are based on different actuarial approaches to calculating an actuarially equivalent value (for example, adjusting for outliers by using the median allowed amounts of the various provider specialties) if the different approach reflects an actuarially acceptable approach and avoids disruptive changes (in essence, higher increases to the copayment limit) for beneficiaries and plan designs, consistent with § 422.100(f)(7)(ii)(C). For example, if using the median allowed amount compared to the average allowed amount would result in a lesser increase to the copayment limit from the prior year while still reflecting an actuarially equivalent copayment for the benefit and beneficiary population.
- Not calculating an actuarially equivalent value to be the copayment limit, thus permitting MA plans to analyze their own data on the estimated total MA plan financial liability for that contract year to calculate the dollar amount that is actuarially equivalent to the applicable coinsurance percentage and establish the MA plan's copayment at or below that dollar amount. Each of these potential outcomes would include compliance with § 422.100(f)(7)(iii), which provides for an opportunity for public notice and comment.

By applying the requirements in § 422.100(f)(6)(iii), (f)(7), and (f)(8) to recalibrate copayment limits based on Medicare FFS data projections on an annual basis, we will ensure copayment limits continually align with the coinsurance limits for service categories subject to paragraphs (f)(6)(i), (iii), and (j)(1) in future years. As discussed in section II.A. of this FC, we are also annually recalibrating MOOP limits based on Medicare FFS data projections to accurately reflect changes in expected costs, subject to the limit on changes in the MOOP limit of more than 10 percent from one year to the next. We believe that updates of this type are

appropriate to carry out the goal of the February 2020 proposed rule to continue balancing limits on enrollee cost sharing and changes in benefits with maintaining beneficiary access the affordable and sustainable benefit packages and protecting against discriminatory cost sharing. The methodology in this FC coordinates the updates to the MOOP limits and cost sharing standards for contract year 2023 and future years.

In summary, as discussed in the February 2020 proposed rule, we believe providing MA organizations with the cost sharing flexibilities in § 422.100(f)(6)(iii) will ultimately act as an incentive to encourage more favorable benefit designs for beneficiaries. While we are finalizing transitions to the proposed coinsurance and copayment limits in paragraphs (f)(6)(iii)(C) – (F) and (f)(8), we do not expect the breadth of cost sharing flexibilities will be substantially limited between the three MOOP types during the transition. Specifically, we believe the policies in this FC may incentivize MA organizations to design favorable benefit packages such as through establishing lower or intermediate MOOP amounts and adopt cost sharing that is lower or comparable when compared to existing benefit packages while protecting enrollees from significant annual changes during the transition period.

With respect to the commenter's concern about MA plans being challenged to satisfy the total beneficiary cost (TBC) standard if cost sharing requirements are changed to the range of cost sharing limits proposed in a single year, the TBC standard evaluates year-over-year plan changes in premiums and benefits for purposes of CMS's review and acceptance of bids. The TBC change threshold is determined each year based on a number of factors. CMS has authority to reject bids that propose significant increases in beneficiary costs or decreases in benefits under § 422.254 and uses the TBC evaluation to identify bids that make such significant changes compared to the prior year. See also section 1854(a)(5)(C)(ii) of the Act and § 422.256(a). The TBC threshold for contract year 2021 was increased to account for changes in ESRD enrollment policy and to provide greater flexibility to MA plans in navigating related MOOP limit

changes⁴⁰. The TBC threshold for contract year 2022 was maintained from contract year 2021⁴¹. CMS released an HPMS memorandum titled "Preliminary Contract Year 2023 Part C Benefits Review and Evaluation" on March 3, 2022 (with a comment period) that includes potential changes to the TBC threshold for contract year 2023. CMS will also consider soliciting comment on how CMS sets the TBC threshold for contract year 2024 and future years, if necessary. By finalizing the multiyear transition to the proposed range of cost sharing limits based on the MOOP type in § 422.100(f)(6)(iii) and (f)(8), we do not expect unreasonable challenges for an MA organization to satisfy the TBC evaluation. We intend to continue use of the TBC evaluation to make sure enrollees who continue enrollment in the same plan are not exposed to significant cost increases.

<u>Comment:</u> A commenter requested CMS add cost sharing limits for observation services and ambulance services, and clearly differentiate the maximum copayment limits for these services by the type of MOOP limit.

Response: Ambulance services and observation services (as bundled services under outpatient hospital services) are not inpatient services (§ 422.100(f)(6)(iv)), and are not necessarily professional services (paragraph (f)(6)(iii)), or among the specified categories of services for which cost sharing must not exceed the cost sharing in original Medicare (§ 422.100(j)(1)). Therefore, cost sharing for these services must comply with § 422.100(f)(6)(i) and may not exceed 50 percent coinsurance or actuarially equivalent copayment values (including copayment limits calculated by CMS as discussed in section II.B.5.a. of this FC). The MA plan must not pay less than 50 percent of the estimated total MA plan financial liability for that contract year for these benefits. MA plans may design their benefit package to: (1) apply one cost sharing amount for all observation services; or (2) apply cost sharing based on the

⁴⁰ See the HPMS memorandum titled "Final Contract Year 2021 Part C Benefits Review and Evaluation," issued April 8, 2020.

⁴¹ See the HPMS memorandum titled "Final Contract Year 2022 Part C Benefits Review and Evaluation," issued May 20, 2021.

individual services provided during the observation stay (for example, cost sharing amount for each specialist visit and cost sharing for diagnostic services). If a plan applies cost sharing based on individual services provided during the observation stay, it is possible that some of those services may be subject to CMS service category cost sharing standards in paragraph (f)(6)(iii) or paragraph (j)(1). In addition, ambulance services are not subject to the cost sharing limit proposed and finalized for § 422.113(b)(2)(v) because they are not within the definition of emergency services at paragraph (b)(1)(ii). We direct the commenter to the comments and responses about § 422.113 and cost sharing requirements for emergency services in section II.B.5.d. of this FC and to § 422.113(a), which requires MA organizations to be responsible for ambulance services where other means of transportation would endanger the beneficiary's health. CMS will monitor cost sharing structures and implementation of this regulation; as necessary, we will consider future rulemaking to change the limits applicable to these services, if appropriate.

Comment: A few commenters who were opposed to establishing a range of cost sharing limits based on the type of MOOP stated that this proposal would make comparing and choosing between health plan options more difficult for beneficiaries. Commenters stated MA plan benefits should be more standardized from a consumer advocacy perspective. These commenters also noted CMS should not establish varying cost sharing limits for various service categories in order to avoid placing more burden on the beneficiary to understand complicated coverage terms.

Response: We do not expect that calculating a range of cost sharing limits that are based on the MOOP type established by the MA plan would make comparing and choosing a plan more difficult for beneficiaries. CMS expects that beneficiaries may consider the MOOP amount, cost sharing amounts, along with many other factors such as perception of brand, premium, plan type, benefits, quality ratings, and provider network when choosing a health care plan⁴², and this

⁴² Milliman. October 2020. "Star Rating Changes: How Medicare Advantage Plans React" may be accessed at: https://us.milliman.com/en/insight/Star-rating-changes-How-Medicare-Advantage-plans-react.

information will continue to be available as they review their MA plan options for the upcoming contract year. From a beneficiary perspective, the individual will have the ability to review information about the MOOP amounts and cost sharing structures used by MA plans as they review their coverage options. We do not expect beneficiaries to learn or be aware of the options and flexibilities that MA organizations have to establish certain MOOP types and cost sharing amounts. Rather, we expect they will mostly compare the specific benefit and cost sharing designs from the MA plans that are available to them. In addition, we expect that the incentives in this FC for MA plans to establish copayment amounts over coinsurances will ultimately improve transparency for MA beneficiaries to understand expected cost sharing between plans if MA organizations increasingly use copayments in their bid designs.

CMS does not expect MA organizations to necessarily offer more plan options than they currently do as a result of this provision. MA organizations are not required to offer plans that use each MOOP type and cost sharing possibility. In our experience, MA organizations typically limit the number of plan options in their product portfolio to avoid beneficiary confusion in considering the options. For example, in past years (including contract year 2021) most MA organizations offer an average of 2 to 3 plans per plan type in each service area (excluding employer, D-SNP, and MSA plans). We expect this rule on cost sharing standards will: (1) promote transparency for those who care to learn how CMS calculates copayment limits; and (2) incentivize MA organizations to offer MA plans with lower MOOP limits by aligning the cost sharing limits based on the MOOP type established by the MA plan with lower MOOP limits having the most cost sharing flexibility, which may benefit enrollees. In addition, CMS will continue conducting reviews and enforcing its current authority prohibiting plans from misleading beneficiaries in their marketing and communication materials and activities and continue to improve plan comparison tools and resources (for example, Medicare plan finder, Medicare & You and 1-800-MEDICARE).

Comment: Several commenters raised concerns regarding discrimination against beneficiaries with high or specific health care needs. A few commenters opposed the proposal to allow MA plans with lower MOOP limits to establish up to a 50 percent coinsurance and indicated that requiring such significant cost sharing would make obtaining medically necessary care out of reach, financially, for a large number of beneficiaries. A commenter explained that the majority of Medicare beneficiaries live on limited fixed incomes and have little or no savings. As such, the commenter believed these beneficiaries would not be able to access medically necessary care because cost sharing amounts are unaffordable. The commenters, however, did not suggest an alternative safeguard for CMS to use to protect against this type of harm; rather the commenters seem to suggest that CMS should not finalize the proposal to permit cost sharing up to 50 percent of the total MA plan liability for a service in any situation. Another commenter suggested CMS be cautious about increased cost sharing for an already vulnerable patient population but did not specifically tie that concern to a particular proposal; the commenter expressed concern that high cost sharing levels discriminate against enrollees who need those services.

A commenter opposed CMS's proposal to allow MA plans that establish a lower MOOP limit to set cost sharing as high as 50 percent or the actuarially equivalent copayment limit (projected as \$85 in the February 2020 proposed rule) for physical therapy and speech-language pathology. The commenter was concerned that permitting cost sharing at these levels would result in MA plans establishing cost sharing that would pose a significant financial burden and barrier to access for beneficiaries who need those services, particularly for services such as physical therapy that are typically associated with a higher frequency in visits. In reference to those concerns, the commenter requested that CMS: (1) acknowledge the reality of the financial implications of copays that are required for each physical therapist visit on beneficiaries; (2) add physical therapy to the list of services for which an MA plan may not exceed cost sharing required under original Medicare (to make the cost sharing limits more reasonable for physical

therapy services); and (3) set lower cost sharing limits for all categories of services that have a higher frequency in visits. The commenter noted appreciation for CMS's rationale for allowing greater flexibility and that CMS will, in its annual review of plan cost sharing, monitor both copayment amounts and coinsurance percentages; however, the commenter had serious concerns with the cost sharing MA plans have imposed for physical therapy. This commenter acknowledged that MA plans may establish one cost sharing amount for multiple visits provided during an episode of care (for example, several sessions of cardiac rehabilitation) as long as the overall cost sharing amount satisfies CMS standards. However, the commenter noted they were not aware of any plans that have adopted one cost sharing amount for multiple visits provided during a physical therapy episode of care. In addition, this commenter stated that some enrollees have reported paying copayments that were higher than the amount the enrollee's Explanation of Benefits showed as the MA plan's payment to the physical therapist; the commenter gave the example of an MA plan reimbursing the physical therapist \$25 while the enrollee's copay was \$65 for each visit. In addition, the commenter reported the cost sharing established by MA plans for physical therapy imposes a significant barrier to care for beneficiaries and copayments for physical therapy are frequently cited as a reason that some consumers opt to reduce their frequency of care or forgo medically necessary care. The commenter compared the impact of higher cost sharing for physical therapy in relation to primary care and other specialist providers to illustrate the concern that high cost sharing for repetitively utilized services discriminates against patients who need such services. Enrollees typically require multiple physical therapy visits over an extended period to properly recover from an injury or alleviate symptoms related to an acute or chronic condition, while visits to primary care providers and other specialists are typically less frequent. Based on that utilization difference, the commenter noted that higher cost sharing requirements for physical therapy create a significant financial burden for enrollees in need of multiple visits for a full recovery and may be a deterrent to accessing care. The commenter stated that as a consequence of high physical therapy cost sharing, enrollees who fail

to receive the rehabilitative care they need from a physical therapist are more likely to require higher-cost interventions to remain functional — potentially resulting in the development or recurrence of severe functional impairments and downstream costs, including surgery, imaging, and pharmacy.

Response: We appreciate the commenters' feedback and acknowledge the concerns about higher cost sharing being a significant financial burden for beneficiaries. As discussed in the February 2020 proposed rule, the policy requiring MA organizations to pay at least 50 percent of the total plan financial liability for benefits has been in place for some time and has its origins in prohibiting discrimination against individuals based on health status, particularly discriminating against beneficiaries that need the particular benefit for which the plan payment is a smaller percentage of the total cost. In our proposal and this FC, we limit this flexibility to use 50 percent cost sharing for in-network professional services to MA plans with lower MOOP limits. In addition, we are codifying the prohibition on cost sharing that exceeds 50 percent of the estimated total MA plan financial liability for that contract year for Part A and Part B benefits that are furnished by an out-of-network provider.

As discussed previously in a response to comment in this section, based on comments and further consideration of strategies CMS can employ to avoid potential disruption for enrollees and plan designs, we are finalizing a 4-year transition from contract year 2022 cost sharing limits to the 30, 40, and 50 percent coinsurance and related actuarially equivalent copayments for professional services that are Part A and B benefits (that is, basic benefits) proposed in § 422.100(f)(6)(iii). The cost sharing limits resulting from the first year of applying this transition (contract year 2023) are reflected in Table 28, including for the "physical therapy and speech-language pathology" service category. Compared to the February 2020 proposed rule's illustrative cost sharing limits for the "physical therapy and speech-language pathology" service category (30 percent/\$50, 40 percent/\$65, and 50 percent/\$85 for the mandatory, intermediate, and lower MOOP limit respectively), the final contract year 2023 copayment limits

(as shown in Table 28: 45 percent/\$45, 47 percent/\$50, and 50 percent/\$50 for the mandatory, intermediate, and lower MOOP limit respectively) are substantively lower due to the transition and "lesser of" requirement finalized in § 422.100(f)(8). We used contract year 2023 Medicare FFS data projections (based on 2017 – 2021 Medicare FFS data) to calculate the final cost sharing limits for contract year 2023. The calculations CMS made to reach these final contract year 2023 copayment limits for the "physical therapy and speech-language pathology" service category (for plans that establish a mandatory MOOP limit) are available in Table 14B. Similar calculations were made to reach the final contract year 2023 copayment limits in Table 28 for the other professional service categories and types of MOOP limits.

Although this rule continues to permit certain MA plans to have cost sharing obligations of up to 50 percent for certain basic benefits, the cost sharing standards and the MOOP limit requirements (section II.A. of this FC) will apply together to protect enrollees. We expect this, in conjunction with the other cost sharing standards being finalized in this FC, to produce a corresponding level of beneficiary and plan incentive that is unique to each type of MOOP limit, because plans with lower MOOP limits receive the most cost sharing flexibility. Under section 1854(a)(5)(C)(ii) of the Act, CMS is authorized to deny a plan bid if the bid proposes significant increases in enrollee costs or decrease in benefits from one plan year to the next. A plan's TBC is the sum of the plan-specific Part B premium, plan premium, and estimated enrollee out-ofpocket costs. The TBC evaluation is applied at the plan level to ensure enrollees in each applicable plan are not subject to too significant an increase in costs or decrease in benefits from one plan year to the next. As stated previously, MA organizations typically offer benefits with lower cost sharing amounts than the annual limits published by CMS; we believe this is due to multiple factors (other than the TBC standard), including the principles and incentives inherent in managed care, effective negotiations between organizations and providers, and market competition. For MA plans that choose to establish the highest level of cost sharing permitted by § 422.100(f)(6), they must also ensure that: (1) total MA cost sharing for all basic benefits,

excluding out of network benefits covered by a regional MA plan, must not exceed cost sharing for those benefits in original Medicare on a per member per month actuarially equivalent basis; (2) for specific basic benefits in § 422.100(j), in-network cost sharing established by an MA plan must not exceed the cost sharing required under original Medicare; and (3) additional cost sharing standards for the plan benefit package service category or for a reasonable group of benefits or services covered under the plan must be met. In addition, in evaluating which benefits would have the highest cost sharing, MA organizations must be mindful not to discriminate against enrollees based on health status. For example, for contract year 2019,⁴³ the cardiac and pulmonary rehabilitation service categories (utilized by enrollees with certain health conditions such as heart failure and Chronic Obstructive Pulmonary Disease (COPD)) were areas of concern and CMS conducted additional scrutiny of MA plans with higher cost sharing amounts for those services to ensure that the plan designs were not discriminatory. CMS has the authority to continue to evaluate plans for potential discrimination through these mechanisms as discussed is section II.B.5.a. of this FC.

We note the example provided by a commenter of a \$65 copayment for a physical therapy visit is above the \$40 copayment limit for the in-network "physical therapy and speech-language pathology" service category for approved bids for contract year 2020 (which was in effect at the time of the public comment period and for contract year 2021 and 2022). MA organizations contract with providers, including physical therapists, to provide services to enrollees. The terms of contractual arrangements include provider reimbursement, which may also include enrollee cost sharing that the provider is permitted to collect. If enrollees believe that an MA organization is not providing adequate access to services or its contracted providers are not billing enrollees correctly, complaints may be submitted online⁴⁴ or by calling 1-800-

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⁴³ See page 202 of the CY 2019 Final Call Letter at: https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2019.pdf.

⁴⁴ The online Medicare Compliant Form may be accessed and submitted at: https://www.medicare.gov/medicarecomplaintform/home.aspx.

MEDICARE. CMS monitors and investigates complaints related to plan coverage and CMS caseworkers assist in the resolution of issues with MA organizations. To protect enrollees, CMS may take compliance or enforcement actions against an MA organization for failing to meet any contract requirements, such as providing adequate access to medically necessary services, as warranted. In addition, enrollees who have complaints about their MA plan may file a grievance under § 422.564 and, if they believe that benefits have been improperly denied, file an appeal under the rules in §§ 422.562 through 422.619.

We appreciate the feedback and are finalizing our proposals for cost sharing for professional services with moderate modifications; we are finalizing the methodology used to calculate MA cost sharing standards for professional services and calculating a range of cost sharing limits for benefits furnished on an in-network basis based on the MOOP type established by the MA plan. The modifications include using a 4-year transition to the proposed 30, 40, and 50 percent coinsurance and actuarially equivalent copayment limits (finalized at § 422.100(f)(6)(iii) and (f)(8)). In addition, we are finalizing various edits and restructuring of the regulation text to improve clarity in the regulations. By implementing more than two levels of MOOP limits and limiting the scope of services on which the highest allowable cost sharing could be imposed (50 percent), we expect to encourage plan offerings with favorable benefit designs so that beneficiaries can choose MA plans that meet their needs. CMS will monitor whether changes from this FC result in beneficiaries having access to plan offerings with MOOP limits below the mandatory MOOP limit and lower or comparable cost sharing when compared to existing benefit packages over time.

This rule is focused on addressing particular ways that cost sharing structures could be used to discourage enrollment by beneficiaries with significant or costly health needs.

Prohibitions on discrimination continue to apply in the MA program and CMS takes its role in guarding against discrimination on the basis of health status seriously. CMS reviews cost sharing based on the current limits that are intended to address discrimination based on health

needs and based on other standards regulating cost sharing, such as requirements in current § 422.100(j) and (k) for certain services to have cost sharing that does not exceed cost sharing in original Medicare. CMS will incorporate the standards adopted in this FC into those reviews, beginning with reviews of bids for contract year 2023. We will not approve a plan bid if its proposed benefit design substantially discourages enrollment in that plan by certain Medicareeligible individuals, and cost sharing structures are an important consideration in our reviews. For example, CMS analyzes plan bid submissions to evaluate whether cost sharing levels satisfy MA requirements and are defined or administered in a manner that may discriminate against sicker or higher-cost beneficiaries. These analyses also may evaluate the impact of benefit design on beneficiary health status and/or certain disease states. CMS contacts MA organizations to discuss any issues that are identified in MA plan bids as a result of these analyses and seeks correction or adjustment of the bid as necessary. CMS is not required to accept every bid and has authority to negotiate the benefits offered by MA plans under section 1854(a)(5) and (6) of the Act. CMS will also continue evaluations and enforcement of the current authority prohibiting plans from misleading beneficiaries in their communication materials and continue efforts to improve plan comparison tools and resources (for example, Medicare Plan Finder, Medicare & You, and 1–800–MEDICARE).

In CMS's experience, for the most part MA organizations typically offer benefits with lower cost sharing amounts than the standards CMS calculates. However, we are concerned about benefit designs that have in-network cost sharing at the highest allowable level for a subset of benefits, including mental health services as discussed in section III. of this FC. In light of these concerns, we are considering whether cost sharing limits for mental health care, such as mental health specialty services, psychiatric services, partial hospitalization, opioid treatment program services, and treatment for substance use disorders should be subject to additional cost sharing limits, such as a requirement that cost sharing for those service not exceed cost sharing in original Medicare. As discussed in section III. of this FC, we seek comments for consideration

should we choose to pursue future rulemaking on this topic. While we do not expect to release new rulemaking on this topic in time to apply to contract year 2023, we will rely on our existing authority to closely review plan designs for potential disparity in cost sharing for mental health and psychiatric services compared to other professional services and to review significant increases in enrollee costs. CMS may not approve a plan if the MA organization cannot sufficiently explain how their plan design is not discriminating against beneficiaries that need mental health and psychiatric services.

c. Cost Sharing Limits for Inpatient Hospital Acute and Psychiatric Services (§ 422.100(f)(6)(iv))

Comment: A few commenters were generally supportive of CMS's proposals in section VI.B.2. of the February 2020 proposed rule related to inpatient hospital acute and psychiatric services. A commenter supported CMS adding a 3-day length of stay scenario for inpatient hospital acute services and an 8-day length of stay scenario for inpatient hospital psychiatric services. This commenter noted that inpatient hospital services have a high Medicare utilization and therefore provide a large actuarial value and greater incentive for a plan to choose to establish a lower (previously "voluntary") MOOP limit.

Response: We thank commenters for supporting our proposal related to additional length of stay scenarios for inpatient hospital acute and psychiatric services and differentiating the cost sharing limits by the MOOP type established by the MA plan. We agree that permitting greater variation in cost sharing for inpatient hospital services may provide an incentive for MA organizations to offer plans with lower MOOP types. This flexibility allows MA organizations to vary cost sharing for highly utilized services in exchange for a lower MOOP amount that may better meet enrollee needs.

We are finalizing \S 422.100(f)(6)(iv) and (f)(6)(iv)(A) – (D) with additional edits to consistently use the same language to reference the inpatient hospital acute and psychiatric service categories for which CMS calculates cost sharing limits and the length of stay scenarios

used by CMS to evaluate plan cost sharing for those inpatient scenarios. Cost sharing for innetwork basic benefits that are inpatient hospital acute and psychiatric service categories must not exceed a specified percentage of original Medicare cost sharing for the length of stay scenarios based on original Medicare cost sharing for a new benefit period. As finalized in paragraph (f)(6)(iv)(A), this requirement is subject to new paragraph (f)(7) (discussed in detail in section II.B.5.a. of this FC). In brief, this means that the inpatient hospital cost sharing limits are calculated (and plan cost sharing amounts are evaluated) using generally accepted actuarial principles and practices (as finalized in paragraph (f)(7)(i)). In addition, the inpatient hospital cost sharing limits for contract year 2024 and future years will be issued annually through the subregulatory process in paragraph (f)(7)(iii). In paragraph (f)(6)(iv)(B), we are not finalizing the reference to an inpatient facility as we believe individuals could interpret the word facility in a stricter fashion than how the cost sharing limits will be applied; finalizing paragraph (f)(6)(iv)(B) without this reference will more accurately reflect how the cost sharing limits in paragraph (f)(6)(iv) work and how MA organizations may deliver inpatient services. In addition, we are revising the descriptions of the length of stay scenarios to focus on the purpose of the stay (acute versus psychiatric). We are finalizing the proposed rounding rules for inpatient hospital acute and psychiatric cost sharing limits in paragraph (f)(6)(ii) and we are not including a reference to those rounding rules in paragraph (f)(6)(iv) because we believe paragraph (f)(6)(ii) is sufficiently clear about when the rounding rules apply.

We clarify in § 422.100(f)(6)(iv)(C) that CMS calculates the inpatient hospital acute and psychiatric service category cost sharing limits annually using projections of out-of-pocket costs and utilization for the applicable year and length of stay scenario and factors in out-of-pocket costs incurred by beneficiaries with diagnoses of ESRD on the transition schedule described in paragraphs (f)(4)(vi)(A) through (B); the cross reference is updated from the proposed reference to paragraphs (f)(4)(vii)(A) through (D) based on reorganization of the regulation text addressing the ESRD cost transition, as discussed in section II.A. of this FC. In addition, we removed the

reference to exceptions for MOOP limit calculations in paragraphs (f)(4)(v)(A) and (C) in paragraph (f)(4)(iv)(C) as this FC does not include the provision that delays the schedule of incorporating ESRD costs into the methodology CMS uses to calculate MOOP limits (as discussed in section II.A. of this FC). This means that CMS is calculating the inpatient hospital acute and psychiatric service category cost sharing limits for contract year 2023 using projected Medicare FFS beneficiary out-of-pocket spending, which necessarily includes both costs and utilization data, for beneficiaries without diagnoses of ESRD plus 70 percent of the ESRD cost differential. Then, for contract year 2024 and subsequent years CMS will calculate the inpatient hospital acute and psychiatric service category cost sharing limits using Medicare FFS data projections (as defined in paragraph (f)(4)(i), which includes data for beneficiaries with and without diagnoses of ESRD). In addition, as proposed, we are finalizing that CMS may also use patient utilization information from MA encounter data in developing the length of stay scenarios. In summary, CMS implements the inpatient hospital cost sharing limits set in paragraph (f)(6)(iv) by evaluating the plan's cost sharing for each length of stay scenario in comparison to the specific limits that are calculated and published annually (as finalized in paragraphs (f)(6)(iv)(C) and (f)(7)(iii)). Inpatient hospital cost sharing above the annual limits for any one of the length-of-stay scenarios is not permissible.

In finalizing § 422.100(f)(6)(iv)(D), we are including several clarifying modifications. Final paragraph (f)(6)(iv) includes the requirement that the total cost sharing for the inpatient benefit must not exceed the plan's MOOP limit or overall cost sharing for those benefits in original Medicare on a per member per month actuarially equivalent basis. We are not finalizing this provision only in paragraph (f)(6)(iv)(D)(3), which was proposed, because we intend this requirement to apply regardless of the type of MOOP limit used by the MA plan. This modification clarifies our policy and makes paragraph (f)(6)(iv) consistent with our proposal in section VI.B.4. in the February 2020 proposed rule (and finalized in section II.B.5.f. of this FC) to include in § 422.100(j)(2)(i)(A) that MA cost sharing for inpatient hospital acute and

psychiatric services must not exceed the cost sharing in original Medicare (for the period during which original Medicare has cost sharing) on a per member per month actuarially equivalent basis. Our proposal in paragraph (j)(2)(i)(A) was to codify that this requirement applies for any type of MOOP limit. Considering how our proposals in paragraphs (f)(6)(iv) and (j)(2)(i)(A) combine for cost sharing standards for the inpatient hospital service categories, we believe stating this requirement in paragraph (f)(6)(iv)(D) to apply to all MOOP types is clearer and ensures that the overall cost sharing limit policies are consistent.

We are finalizing § 422.100(f)(6)(iv)(D)(1) and (3) with minor modifications to clarify that the cost sharing limits for inpatient hospital acute and psychiatric length of stay scenarios are based on the projected Part A deductible and related Part B costs, which is consistent with the illustrative calculations in the February 2020 proposed rule, the final contract year 2023 inpatient hospital cost sharing limits included in Table 28, and longstanding CMS methodology. Our proposal did not include the word "projected," and we wish to ensure clarity and consistency on this point that the projected Part A deductible and related Part B costs for the applicable year will be used. The February 2020 proposed rule would have permitted MA plans with a lower MOOP amount to establish cost sharing above 125 percent of estimated Medicare FFS cost sharing for the inpatient acute 60-day length of stay, as long as the total inpatient benefit cost sharing does not exceed the MOOP limit or cost sharing for those benefits in original Medicare on a per member per month actuarially equivalent basis. This was proposed as part of paragraph (f)(6)(iv)(D)(3) and is largely being finalized as proposed. Even though the MA plan may use cost sharing that, for this specific 60-day scenario, is higher than 125 percent of original Medicare cost sharing for that scenario, the cost sharing for that length of stay is capped at the lower MOOP amount, and overall cost sharing for inpatient services must not exceed original Medicare cost sharing for that benefit category on a PMPM basis. While CMS provides this flexibility for plans that establish a lower MOOP amount, we expect that the competition to offer plans that attract beneficiaries is an important incentive for MA organizations and will factor into

how MA organizations establish cost sharing for the inpatient hospital benefit portion of the basic benefit package. In summary, the modifications to paragraphs (f)(6)(iv)(D)(1) and (3) include clarifying: (1) the cost sharing for the entire inpatient benefit must not exceed the MOOP amount for the MA plan; (2) projected cost sharing for the Medicare FFS program will be used; and (3) that the flexibility to establish cost sharing above 125 percent of estimated Medicare FFS cost sharing is limited to MA plans with a lower MOOP amount and only to the inpatient hospital acute 60-day length of stay scenario.

We are finalizing § 422.100(f)(6)(iv)(D)(2) with revisions as well. The revised text adjusts inpatient hospital acute and psychiatric cost sharing limits for MA plans that establish an intermediate MOOP limit in order to address flexibilities and unique situations. We proposed that inpatient hospital acute and psychiatric cost sharing limits for MA plans that establish an intermediate MOOP limit be based on the numeric midpoint between the cost sharing limits established for the mandatory and lower MOOP limits. As proposed and finalized in paragraph (f)(6)(iv)(D) and (f)(6)(iv)(D)(3), MA plans with a lower MOOP limit have the flexibility to establish cost sharing above 125 percent of estimated Medicare FFS cost sharing in limited situations (discussed in the previous paragraph). Given this flexibility, we believe the cost sharing limit for MA plans that use an intermediate MOOP limit is more clearly stated as the numeric midpoint between the cost sharing limits established for the mandatory and lower MOOP limits for the same inpatient hospital length of stay scenario, before application of the rounding rules in paragraph (f)(6)(ii). While MA plans that establish a lower MOOP amount have the flexibility to establish cost sharing above 125 percent in limited situations, operationally the cost sharing limit is capped at the lower MOOP amount for that contract year. This will result in all of the inpatient hospital length of stay scenarios having a more precise cost sharing limit for the intermediate MOOP limit as that cost sharing limit will be based on a numeric midpoint between the cost sharing limits set for the mandatory and lower MOOP types (with ESRD costs factored in using the transition schedule in paragraph (f)(4)(vi) as finalized in paragraph

(f)(6)(iv)(C)) after application of the MOOP limit cap. In addition, this revision will avoid the rounding rules in paragraph (f)(6)(ii) being unnecessarily applied twice in the calculation of the inpatient cost sharing limit for MA plans that use an intermediate MOOP type. For example, the cost sharing limits calculated for the inpatient acute 3-day length of stay for the mandatory and lower MOOP limits have already been rounded when calculated to apply to MA plans with those types of MOOP limits and calculating a numeric midpoint between them could produce an amount that requires additional rounding in order to reach a whole dollar amount. In order to address these complexities, we are modifying paragraph (f)(6)(iv)(D)(2), so that cost sharing for the intermediate MOOP limit is based on the numeric midpoint between the cost sharing limits established in paragraphs (f)(6)(iv)(D)(1) and (3) for the same inpatient hospital length of stay scenario. The rounding rules finalized at § 422.100(f)(6)(ii) will then be applied to that dollar amount. This change would not have substantially affected most of the illustrative inpatient hospital acute and psychiatric cost sharing limits that were included in Table 5 (Illustrative Contract Year 2022 In-Network Service Category Cost Sharing Limits) in the February 2020 proposed rule. For example, by using the numeric midpoint between the illustrative copayment limits for the mandatory and lower MOOP types before the application of the rounding rules based on the same data used in the February 2020 proposed rule and the proposed ESRD cost transition schedule, the illustrative contract year 2022 inpatient hospital acute 3-day length of stay scenario cost sharing limit for the intermediate MOOP limit would have been \$2,106 (a \$1 increase from the illustrative amount included in Table 5 from the February 2020 proposed rule). However, using this more precise numeric midpoint would have substantially affected the illustrative inpatient hospital acute cost sharing limit for the 60-day length of stay scenario that was included in Table 5 in the February 2020 proposed rule for the intermediate MOOP limit. The illustrative value for the inpatient hospital acute 60-day length of stay for the intermediate MOOP limit in Table 5 of the February 2020 proposed rule was \$5,514. This value was calculated using the proposed ESRD cost transition schedule and was based on the numeric

midpoint between 125 and 100 percent of estimated Medicare FFS cost sharing for an inpatient hospital acute 60-day length of stay. As a result, the \$5,514 illustrative copayment limit did not reflect the numeric midpoint between the \$4,902 illustrative copayment for the mandatory MOOP limit and the cap of the lower MOOP limit (\$3,450 for contract year 2022 as illustrated in Table 4 of the February 2020 proposed rule) that would be applied in this scenario (reflected as "N/A" in Table 5 of the February 2020 proposed rule). Instead, the illustrative copayment limit for the intermediate MOOP type (based on the same data used in the February 2020 proposed rule and the proposed ESRD cost transition schedule) using the precise numeric midpoint should have been \$4,176 (a \$1,338 decrease from the \$5,514 illustrative amount for the inpatient hospital acute 60-day length of stay scenario included in Table 5 from the February 2020 proposed rule). Using the numeric midpoint between the actual, calculated cost sharing limits (that is the dollar amounts) for the mandatory and lower MOOP types would be consistent with all of the other illustrative inpatient hospital cost sharing limits for all of the other length of stay scenarios applied to the intermediate MOOP. The other cost sharing limits for the intermediate MOOP were not impacted by the cap of the lower or mandatory MOOP limits for the other length of stay scenarios as those amounts did not exceed the illustrative MOOP limits for that contract year. This approach of using the precise numeric midpoint of the cost sharing limits applied to the mandatory and lower MOOP types to calculate the cost sharing limit for the same length of stay scenario for the intermediate MOOP limit, as finalized in paragraph (f)(6)(iv)(D)(2), is reflected in the final contract year 2023 inpatient hospital acute and psychiatric cost sharing limits in Table 28. The figures in Table 28 are calculated using projections of 2017 – 2021 Medicare FFS data and the finalized ESRD cost transition schedule as discussed in a following response to comment in this section.

We believe it is important to reiterate that cost sharing limits applicable for any service category cannot exceed the associated MOOP limit, including the inpatient hospital acute and psychiatric length of stay scenarios as finalized in § 422.100(f)(6)(iv). CMS did not propose to

allow, and would not approve a plan bid that allowed, inpatient hospital cost sharing above the related MOOP amount for that plan. The flexibility to establish cost sharing above 125 percent of estimated Medicare FFS cost sharing for the inpatient hospital acute 60-day length of stay scenario for MA plans with a lower MOOP amount (in paragraph (f)(6)(iv)(D)(3)) is effectively capped at the lower MOOP limit. In addition, if the MA plan establishes a MOOP amount less than the highest allowable lower MOOP limit, then the cost sharing for the inpatient hospital acute 60-day length of stay scenario would also be capped at the MA plan's actual MOOP amount. Consistent with current practice, for MA plans that establish a coinsurance for inpatient hospital standards, supporting documentation must be submitted with the initial bid showing how the plan's coinsurance amount satisfies the standards under § 422.100(f)(6)(iv). This will follow the same process discussed in section II.B.5.a. of this FC for when an MA plan must provide documentation to support its cost sharing and CMS would generally review this documentation as part of its bid evaluation. This is consistent with the overall standard of MA plans not being able to charge the enrollee an amount higher than the MOOP amount they establish.

In Table 5 (Illustrative Contract Year 2022 In-Network Service Category Cost Sharing Limits) from the February 2020 proposed rule, we listed the cost sharing limit for the inpatient hospital acute 60-day length of stay scenario for MA plans that establish a lower MOOP amount as "N/A" to reflect the flexibility MA organizations have in establishing cost sharing above 125 percent of estimated Medicare FFS cost sharing. However, using projections of Medicare FFS data from 2015 - 2019 that was available at the time of writing the February 2020 proposed rule, a cost sharing limit at 125 percent of estimated Medicare FFS cost sharing (plus 80 percent of the ESRD cost differential for contract year 2022 as proposed) would have been \$6,127. This amount is \$2,677 higher than the illustrative contract year 2022 in-network lower MOOP limit of \$3,450 shown in Table 4 (Illustrative Example of In-Network MOOP Limits Based on Most Recent Medicare FFS Data Projections) of the February 2020 proposed rule. The value of 125 percent of estimated Medicare FFS cost sharing using updated projections of Medicare FFS data

(from 2017 – 2021) and the finalized ESRD cost transition schedule for the inpatient hospital acute 60-day length of stay scenario also exceeds the final contract year 2023 lower MOOP limit (\$7,162 compared to \$3,650). In order to be clear about the highest allowable inpatient hospital cost sharing that an enrollee could experience, we updated the "N/A" for the 60-day length of stay scenario to the final contract year 2023 in-network lower MOOP limit amount in Table 28 (that is, \$3,650 as listed in Table 5 and discussed in section II.A. of this FC). The complete list of final contract year 2023 inpatient hospital cost sharing limits is available in Table 28, which were calculated using the rules finalized in § 422.100(f)(6)(iv) and the data described in § 422.100(f)(4)(vi)(A) (that is, projected Medicare beneficiary out of pocket spending for 2023 for beneficiaries without diagnoses of ESRD plus 70 percent of the ESRD cost differential).

MA plans that establish a lower MOOP amount will effectively have a cost sharing limit for the inpatient acute 60-day length of stay scenario that is calculated at the in-network lower MOOP limit amount whenever the calculations of 125 percent of Medicare FFS cost sharing exceed the lower MOOP limit. The dollar amount which is applied as the cost sharing limit, before rounding, is used in the calculation of the inpatient acute 60-day length of stay scenario cost sharing limit for MA plans that establish an intermediate MOOP limit (as discussed previously in this response and finalized in § 422.100(f)(6)(iv)(D)(2)). The cost sharing limits for the intermediate MOOP limit will be calculated using the numeric midpoint of the cost sharing limits established for the mandatory and lower MOOP limits, consistent with proposed § 422.100(f)(6)(iv)(D)(2). Based on the methodology finalized to calculate the cost sharing limit for an inpatient acute hospital 60-day length of stay for the intermediate MOOP limit and the projections of Medicare FFS out-of-pocket costs and utilization based on 2017 - 2021 Medicare FFS data and using 70 percent of the ESRD cost differential, the associated cost sharing calculation for contract year 2023 equals \$4,690 after applying the rounding rules in § 422.100(f)(6)(ii). In comparison, the final contract year 2023 in-network intermediate MOOP limit is \$6,000 (as listed in Table 5 and discussed in section II.A. of this FC). As a result, for MA plans with an intermediate MOOP, the final contract year 2023 cost sharing limit for this 60-day length of stay inpatient hospital acute scenario is \$4,690 (as listed in Table 28) as it does not exceed the associated MOOP limit for contract year 2023. CMS will continue this process of comparing cost sharing limits calculated using the methodology in paragraph (f)(6)(iv) to the related MOOP limit before issuing the specific cost sharing limits for inpatient services for contract year 2024 and future years.

In summary, we believe listing specific dollar amounts (instead of "N/A") in Table 28 clarifies and avoids potential confusion about the level of flexibility MA plans have, including those that establish a lower MOOP amount, under § 422.100(f)(6)(iv). Listing the in-network MOOP amounts when applicable for particular inpatient length of stay scenarios in Table 28 and in subregulatory guidance for future contract years does not nullify the requirement that the total cost sharing for the inpatient benefit must not exceed the cost sharing for inpatient benefits in original Medicare on a per member per month actuarially equivalent basis. In addition, CMS provides instructions describing how excess cost sharing is evaluated using BPT information to satisfy the per member per month actuarially equivalent requirement for the benefit categories subject to § 422.100(j)(2) (including inpatient) in section II.B.5.f. of this FC. Our evaluations of the per member per month limits are specific to each MA plan bid and will happen during CMS review of bids, consistent with longstanding practice. For contract year 2024 and future years, instructions on these topics will be provided as part of the annual issuance of subregulatory guidance required by paragraph (f)(7)(iii).

Comment: A commenter generally supported CMS's proposal to consistently implement a multiyear transition of ESRD costs into the methodology CMS uses to set inpatient hospital acute and psychiatric cost sharing limits and MOOP limits. This commenter requested that CMS accelerate the transition of ESRD costs to align with the OACT's projections of how quickly beneficiaries with diagnoses of ESRD may enroll in the MA program and apply the accelerated transition schedule to the methodology CMS uses to set inpatient hospital acute and psychiatric

services cost sharing limits and MOOP limits. The commenter included an example of a shortened schedule CMS could consider that would incorporate the ESRD cost differential as follows: 50 percent in 2021, 75 percent in 2022, and 100 percent in 2023. In addition, a commenter requested CMS release the methodology used for setting inpatient hospital acute and psychiatric services cost sharing limits in subregulatory guidance each year consistent with guidance on the MOOP limit methodology.

Another commenter opposed CMS transitioning any ESRD costs into the methodology CMS uses to set inpatient hospital acute and psychiatric cost sharing limits. The commenter noted that by transitioning ESRD costs into the methodology that CMS uses to establish cost sharing limits for the 60-day length of stay scenario for inpatient hospital acute services, the resulting maximum cost sharing limits exceed 100 percent of the Medicare FFS cost sharing for individuals without diagnoses of ESRD. They explained that this results in cost sharing limits for the inpatient hospital acute service category that are not actuarially equivalent for the population of beneficiaries without diagnoses of ESRD and including ESRD costs in the methodology CMS uses to set inpatient hospital acute and psychiatric cost sharing limits could cause unintended disruption or unmanageable costs for beneficiaries without diagnoses of ESRD. In addition, the commenter noted establishing inpatient hospital cost sharing limits that are not actuarially equivalent for the non-ESRD population is illustrative of the concerns they have in general with the changes CMS proposed to address the increased MA plan cost due to changes in eligibility for beneficiaries with ESRD. The commenter explained that the changes CMS proposed involve various forms of cost subsidization by enrollees without diagnoses of ESRD, such as use of the ESRD subsidy in the Bid Pricing Tool (BPT), MOOP limit increases, and increases in Part C cost sharing limits. The commenter believed this non-ESRD enrollee cost subsidization will financially strain MA organizations and beneficiaries, and as a consequence, may reduce competition and beneficiary choice.

Response: We appreciate the feedback on our proposed schedule of transitioning ESRD costs into the methodology CMS uses to calculate cost sharing limits for inpatient hospital acute and psychiatric services and have taken these concerns and suggestions under consideration. We agree that the ESRD cost transition should be consistently applied to both methodologies: for calculating cost sharing for inpatient hospital services and for calculating MOOP limits. This use of a consistent transition and approach to incorporating the ESRD costs will provide stability to MA organizations as they can anticipate changes for the upcoming years. In addition, a consistent application will ease administrative burden (by avoiding an overly complicated methodology) and be more transparent and understandable to stakeholders. As discussed in section II.B.5.b. and e. of this FC, the actuarially equivalent copayment transition in § 422.100(f)(8) is only applicable to service categories subject to § 422.100(f)(6)(iii) and (j)(1). Specifically, we are not incorporating an actuarially equivalent copayment differential (finalized in paragraph (f)(8)(i) to the inpatient services cost sharing standards in paragraph (f)(6)(iv). Combining the ESRD cost and actuarially equivalent copayment transitions would result in an overly complicated methodology for the cost sharing limits for inpatient hospital acute and psychiatric services. Further, we proposed a specific and separate methodology (the ESRD cost transition) in order to mitigate potentially disruptive changes to the cost sharing limits for inpatient hospital acute and psychiatric services. We believe our final policy for paragraph (f)(6)(iv) (discussed subsequently in this response) is sufficient to mitigate disruptive changes.

We agree that inpatient acute cost sharing limits are projected to continue increasing at a greater rate than if ESRD costs were excluded and understand the commenter's concern about non-ESRD enrollees subsidizing the costs related to the expansion of enrollment into the MA program by beneficiaries with diagnoses of ESRD. However, the 21st Century Cures Act required CMS to lift the enrollment restrictions for beneficiaries with diagnoses of ESRD beginning in 2021 and those beneficiaries are now eligible for MA enrollment on the same basis as other beneficiaries. Setting up separate benefit structures by using different cost sharing for

MA enrollees based on whether they have been diagnosed with ESRD is not consistent with the Medicare statute, particularly sections 1852 and 1854(c) of the Act. Beneficiaries with diagnoses of ESRD are entitled to Medicare and therefore entitled to the same benefits and benefit options as other beneficiaries. The plan benefit package (PBP) portion of the bid requires uniformity in benefits and cost sharing pursuant to the uniformity requirements in §§ 422.4 (the definition of an MA plan), 422.100(d) and 422.254(b)(2). Characterizing benefit analysis by pitting healthier enrollees against sicker enrollees ignores the uniformity requirements and would discourage enrollment by less healthy beneficiaries into MA plans. Our approach to incorporate costs of beneficiaries with diagnoses of ESRD in setting inpatient hospital cost sharing limits is consistent with the approach CMS has historically used of spreading the burden of medical costs across all potential MA enrollees uniformly through the continued use of the projected Part A deductible and related Part B costs for the population that is eligible to enroll in an MA plan. In addition, we proposed to transition ESRD costs over multiple years in a transparent and standardized approach to avoid sudden, significant disruption and unexpectedly higher costs for beneficiaries. Specifically, we expect conducting a multiyear transition of ESRD costs into our methodology to calculate MOOP and cost sharing limits is an important and necessary step to ensure plan designs are not discriminatory and protect beneficiaries from significant changes in financial costs regardless of the MA plan they choose. Bids are based on the projected revenue requirements of the MA plan to furnish benefits to the expected enrollee population of the plan. MA plan payments for enrollees with ESRD include separate (higher) ESRD capitation rates and an ESRD risk adjustment model for furnishing covered benefits on a uniform basis.

CMS acknowledges and understands that some plans may adopt the mandatory MOOP limit, raise cost sharing for specific benefits where possible under the new cost sharing limits in this FC, or increase enrollee premiums, in part due to the costs they expect to incur to cover services for their enrollees. While some MA organizations have experience managing the health care services for beneficiaries with diagnoses of ESRD under the prior enrollment policy and

during the first year of expanded enrollment eligibility, our proposal and the final policies provide incentives to MA organizations to adopt MOOP limits below the mandatory level and establish lower or comparable cost sharing when compared to existing benefit packages and utilize effective risk mitigation strategies. Our MOOP limit provision in section II.A. of this FC and the cost sharing limit policies addressed in section II.B. of this FC do not limit market competition and we expect beneficiary choice will continue to act as an incentive for MA organizations to offer favorable benefit designs. For example, we expect beneficiary choice will continue to drive MA organizations to offer supplemental benefits, such as vision and dental services. In addition, MA organizations can use multiple strategies to manage care and costs through provider contracting, reinsurance, care coordination, case management, plan benefit designs, and benefit flexibilities including additional telehealth benefits, Special Supplemental Benefits for the Chronically Ill (SSBCI), and our reinterpretation of the MA uniformity requirement (§ 422.100(d)(2)(ii)). We direct commenters to the June 2020 final rule (85 FR 33796) for how CMS finalized policies related to reinsurance (section IV.A.), SSBCI (section II.A.), and kidney acquisition costs (sections III.B. and III.B.) In addition, under section 1854(a)(5)(C) of the Act, CMS is authorized to deny a plan bid, including if it determines the bid proposes significant increases in enrollee costs or decrease in benefits from one plan year to the next. CMS is also authorized to negotiate with MA organizations regarding their bids by section 1854(6)(B) of the Act. The cost sharing requirements adopted under this FC reflect what is minimally acceptable, for the various reasons discussed in detail throughout the February 2020 proposed rule and this FC, and by codifying them in regulations, these standards are transparent for MA organizations. If an MA organization's bid represents too significant an increase in costs or decrease in benefits from the prior year, we have an established evaluation to identify that and engage with the MA organization to revise its bid. A plan's TBC is the sum of the plan-specific Part B premium, plan premium, and estimated enrollee out-of-pocket costs. CMS uses the TBC standard to evaluate year over year changes when bids are submitted for the upcoming contract

year. The TBC standard is applied at the plan level to ensure enrollees in each applicable plan are not subject to too significant an increase in costs or decrease in benefits from one plan year to the next. Because of the availability of these strategies and plan requirements, we do not expect that MA organizations will automatically pass on the anticipated increased costs associated with enrollees with diagnoses of ESRD onto the MA population as a whole. In fact, CMS has observed that historically MA organizations tend to reduce their profit margins, rather than substantially change their benefit package from one year to the next. While we appreciate the commenter's suggestion to align the ESRD cost transition schedule with OACT's projected rate of ESRD enrollment, we believe this would add another layer of complexity and potentially delay the transition process. As discussed in section II.A. of this FC, we did not propose to set the schedule for transitioning ESRD costs into MOOP and inpatient hospital cost sharing limits based upon OACT's projection of ESRD enrollment because actual enrollment per plan may vary and OACT's analysis reflects expectations for the MA program as a whole. As discussed in the February 2020 proposed rule, the OACT expected ESRD enrollment in MA plans to increase by 83,000 beneficiaries as a result of the 21st Century Cures Act provision. The OACT assumed the increase would be phased in over 6 years, with half of those beneficiaries (41,500) enrolling during 2021; the remaining 41,500 additional beneficiaries were expected to enroll in MA plans during the years 2022 to 2026 under the assumption that the number of additional enrollees who have diagnoses of ESRD will continue to increase during that time frame though at a decreasing rate in later years. Based on actual 2021 enrollment data, the OACT continues to project that 83,000 beneficiaries with diagnoses of ESRD will enroll in the MA program over 6 years. If CMS were to match the transition of incorporating ESRD costs to that of OACT's enrollment projections, we would be forced to delay the full transition of ESRD costs until 2026. After publication of the February 2020 proposed rule, CMS announced that it would take the Medicare FFS costs of beneficiaries with diagnoses ESRD into account in developing MOOP and cost

sharing limits for 2021⁴⁵. The contract year 2021 inpatient hospital cost sharing limits (which encompassed 40 percent of the ESRD cost differential) were maintained for contract year 2022 while enrollment of beneficiaries with diagnoses of ESRD is projected to increase⁴⁶. As a result, CMS believes any further delays to the ESRD cost transition would not be beneficial as only 40 percent of the ESRD cost differential has been incorporated up to contract year 2022, the year the OACT projected total enrollment of beneficiaries with diagnoses of ESRD into the MA program to exceed 50 percent. In addition, when developing our proposed ESRD cost transition schedule, we considered how OACT's aggregate projections may not reflect the experiences in all geographic locations, which could have different rates of transition and changes in expenditures for providing care to beneficiaries with diagnoses of ESRD. Given these factors, we are not incorporating the request to set the schedule of transitioning ESRD costs into MOOP and cost sharing limits based exactly on OACT's projection of ESRD enrollment.

For 2021, CMS set the voluntary and mandatory MOOP limits by applying the standard in current §§ 422.100(f)(4) and (5) and 422.101(d)(2) and (3). Because of the expected changes in enrollment in MA plans by beneficiaries with diagnoses of ESRD, we incorporated 40 percent of the ESRD cost differential for 2021 which increased both types of MOOP limits from 2020. The proposed 3-year transition schedule would have incorporated the ESRD cost differential as follows: 60 percent in 2022; 80 percent in 2023 or next year; and 100 percent in 2024 or the final year of transition. Our proposal attempted to strike a balance between providing plan stability while also protecting enrollees from rapid and significant cost and benefit changes. Based on the timing of this FC, the contract year 2021 MOOP limits were maintained for contract year 2022 (applying the existing standard in current §§ 422.100(f)(4) and (5) and 422.101(d)(2) and (3)). As a result, for purposes of the regulation text, our finalized methodology utilizes 2023 as the

⁴⁵ See the HPMS memorandum titled "Final Contract Year 2021 Part C Benefits Review and Evaluation," issued April 8, 2020 for information on MOOP limits for contract year 2021.

⁴⁶ See the HPMS memorandum titled "Final Contract Year 2022 Part C Benefits Review and Evaluation," issued May 20, 2021 for information on MOOP limits for contract year 2022.

first year of the ESRD cost transition schedule. As discussed in section II.A. of this FC, we finalized the completion of the ESRD cost transition in the proposed time frame with a slightly lower incorporation of ESRD costs for contract year 2023; this change in schedule will also apply to the methodology CMS uses to calculate the inpatient hospital acute and psychiatric cost sharing limits as proposed and finalized in paragraph (f)(6)(iv)(C). In lowering the ESRD cost differential percentage for contract year 2023 compared to our proposal for 2023, we aim to strike a balance between curbing potential disruptive changes in MOOP and inpatient services cost sharing limits from contract year 2022 and providing MA organizations the ability to continue offering all plan enrollees, regardless of their ESRD status, quality care and service while keeping premiums and cost sharing at non-discriminatory levels. In summary, the final 2year transition schedule we are codifying in paragraph (f)(4)(vi) incorporates the ESRD cost differential into the Medicare FFS data used for setting inpatient cost sharing limits as follows: 70 percent in 2023; and 100 percent in 2024 or the final year of transition. This builds on how CMS has incorporated 40 percent of the ESRD cost differential in setting the inpatient hospital cost sharing limits for 2021 and 2022. This transition schedule of ESRD costs remains a part of the final methodology CMS uses to calculate inpatient hospital cost sharing limits.

As proposed and finalized in § 422.100(f)(6)(iv)(C), the data used to calculate the inpatient hospital acute and psychiatric cost sharing limits will be aligned with the data used to calculate MOOP limits with regard to using the updated transition schedule to incorporate ESRD costs finalized in section II.A. of this FC. In applying this ESRD cost transition schedule, as finalized in section II.A. of this FC, the cross-reference is being updated to paragraph (f)(4)(vi)(A) through (B) and the reference to paragraph (f)(4)(v)(C) is being removed in the final regulation in paragraph (f)(6)(iv)(C). In addition, paragraph (f)(6)(iv)(C) has a slight modification to make the regulation text more consistent with the other modifications to the rules finalized for MOOP and cost sharing limits as discussed in sections II.A and II.B. of this FC. Specifically, the regulation text consistently refers to the out-of-pocket costs "incurred by"

(rather than "representing") beneficiaries with diagnoses of ESRD in describing the Medicare FFS data CMS would be using are projections for the applicable year and length of stay scenario in paragraph (f)(6)(iv)(C). This use of the phrase "incurred by" here is not relevant to the cost sharing that MA plans must count toward the MOOP limit when determining if the MOOP has been reached by a particular enrollee. These changes are consistent with the language finalized in § 422.100(f)(4)(vii), (f)(6)(i)(B), (f)(6)(iii)(B), and (j)(1)(i)(F)(2) to clearly describe how Medicare FFS data projections are being used across MOOP limits and cost sharing standards. These changes are aligned with our proposals, the calculations of the illustrative inpatient hospital acute and psychiatric cost sharing limits from the February 2020 proposed rule, and the final contract year 2023 limits included in Table 28.

As finalized, CMS is applying the ESRD cost transition consistently to the methodology for calculating cost sharing limits for inpatient hospital services and the methodology for calculating MOOP limits to provide stability to MA organizations. We are finalizing the proposal to use the same data and the transition schedule finalized for incorporating the ESRD cost differential that we adopted in connection with the MOOP limits, through the updated reference to paragraphs (f)(4)(vi)(A) through (B) in paragraph (f)(6)(iv)(C). We are not finalizing the tolling provision for incorporating the ESRD cost differential, so there is no need to address that part of the proposal in final § 422.100(f)(6)(iv). Inpatient hospital cost sharing limits for contract year 2021 were finalized through the HPMS memorandum titled "Final Contract Year 2021 Part C Benefits Review and Evaluation" issued April 8, 2020, and are not addressed in this rule; we used 40 percent of the ESRD cost differential to set those cost sharing limits. In addition, the inpatient hospital cost sharing limits were maintained from contract year 2021 for contract year 2022⁴⁷.

⁴⁷ See the HPMS memorandum titled "Final Contract Year 2022 Part C Benefits Review and Evaluation," issued May 20, 2021.

Tables 18 and 19 illustrate how CMS calculated the final contract year 2023 inpatient hospital acute cost sharing limits based on the MOOP type for the 10-day length of stay scenario using the finalized policy in § 422.100(f)(6)(iv) and projections of contract year 2023 costs based on 2017 – 2021 Medicare FFS data. In addition, Tables 20 and 21 provide similar projections for the same inpatient hospital acute 10-day length of stay scenario to illustrate cost sharing limits for contract year 2024 using contract year 2023 Medicare FFS data projections (as projections for contract year 2024 were not available at the time of writing this FC). Tables 20 and 21 illustrate how the completion of the finalized ESRD cost differential transition may affect the inpatient hospital cost sharing limits for contract year 2024. Tables 18 through 21 are similar to Table 4 (Illustrative Example of Cost Sharing Limits Based on Current Medicare FFS Data For Inpatient Hospital Acute 10-day Length of Stay Scenario) in the February 2020 proposed rule, with updates to apply the methodology as finalized for comparison purposes. Specifically, the inpatient hospital cost sharing limits in Tables 18 through 21 were developed by: (1) incorporating 70 percent of the projected ESRD cost differential for 2023 and 100 percent of the ESRD cost differential for 2024 (the final year of the ESRD cost transition); (2) applying the modified methodology to calculate inpatient hospital cost sharing limits for MA plans with an intermediate MOOP limit (as discussed previously in a response to comment in this section); and (3) applying the rounding rules finalized in § 422.100(f)(6)(ii). Similar calculations as shown in Tables 18 and 19 were completed to reach the final contract year 2023 inpatient hospital cost sharing limits for the other length of stay scenarios include in Table 28.

As shown in Tables 18, 19, and 28, modifying the ESRD cost transition from the proposed 80 percent to 70 percent in contract year 2023 and basing the amounts on projections using Medicare FFS data from 2017 - 2021 (compared to the 2015 - 2019 data available at the time of the February 2020 proposed rule) produced an increase from the amounts projected in the February 2020 proposed rule, using the proposed methodology; the highest allowable amount for an inpatient hospital acute 10-day length of stay scenario in contract year 2023 for an MA plan

that establishes a mandatory MOOP amount increased by \$242. However, we reiterate that the contract year 2024 inpatient hospital cost sharing limits in Tables 20 and 21 are illustrative in nature and are subject to update using more recent Medicare FFS data projections when CMS issues the final cost sharing limits for contract year 2024 through the annual subregulatory process in § 422.100(f)(7)(iii). We currently intend to calculate and set contract year 2024 cost sharing limits using contract year 2024 Medicare FFS data projections (based on 2018 – 2022 Medicare FFS data) after publication of this FC, which may vary from the illustrations in Tables 20 and 21.

TABLE 18: CMS CALCULATIONS OF THE FINAL CONTRACT YEAR 2023 INPATIENT HOSPITAL ACUTE 10-DAY LENGTH OF STAY SCENARIO COST SHARING LIMITS FOR THE MANDATORY AND LOWER MOOP TYPES USING PROJECTIONS FROM 2017 – 2021 MEDICARE FFS DATA AND THE ESRD COST DIFFERENTIAL TRANSITION

Row		Mandatory MOOP	Lower MOOP
Reference	Description	Type	Type
A	Projected Part A Deductible*		\$1,572.00
В	Projected Part B Professional Costs for a 10-day length of stay (with ESRD costs)*		\$955.00
С	Total estimated Medicare FFS cost sharing for a 10-day length of stay with ESRD costs (row A plus row B)		\$2,527.00
D	Projected Part B Professional Costs for a 10-day length of stay (without ESRD costs)		\$863.00
Е	Total estimated Medicare FFS cost sharing for a 10-day length of stay without ESRD costs (row A plus row D)		\$2,435.00
F	Allowable percentage of Medicare FFS estimated cost sharing by MOOP type per § 422.100(f)(4)(iv)	100%	125%
G	Total cost sharing with ESRD costs (row C multiplied by row F)	\$2,527.00	\$3,158.75
Н	Total cost sharing without ESRD costs (row E multiplied by row F)	\$2,435.00	\$3,043.75
Ι	ESRD cost differential per § 422.100(f)(4)(vi) (row G - row H)	\$92.00	\$115.00
J	70% of ESRD cost differential per § 422.100(f)(4)(vi) (row I multiplied by 0.7)	\$64.40	\$80.50
K	Unrounded contract year 2023 cost sharing limit (row H plus row J)	\$2,499.40	\$3,124.25
L	Rounded final contract year 2023 cost sharing limit per § 422.100(f)(6)(iv) (row K rounded per § 422.100(f)(6)(ii))	\$2,499.00	\$3,124.00

^{*}The OACT employed generally accepted actuarial principles and practices in calculating this projected amount (as finalized in § 422.100(f)(7).

TABLE 19: CMS CALCULATIONS OF THE FINAL CONTRACT YEAR 2023 INPATIENT HOSPITAL ACUTE 10-DAY LENGTH OF STAY SCENARIO COST SHARING LIMIT FOR THE INTERMEDIATE MOOP TYPE USING PROJECTIONS FROM 2017 – 2021 MEDICARE FFS DATA AND THE ESRD COST DIFFERENTIAL TRANSITION

Row Reference	Description	Intermediate MOOP Type
A	Unrounded contract year 2023 inpatient hospital acute 10-day length of stay scenario cost sharing limit for the mandatary MOOP type per § 422.100(f)(4)(vi) (row K, mandatory MOOP limit column in Table 18)	\$2,499.40
В	Unrounded contract year 2023 inpatient hospital acute 10-day length of stay scenario cost sharing limit for the lower MOOP type per § 422.100(f)(4)(vi) (row K, lower MOOP limit column in Table 18)	\$3,124.25
С	Unrounded contract year 2023 cost sharing limit per § 422.100(f)(6)(iv) (numeric midpoint between row A and row B)	\$2,811.83
D	Rounded contract year 2023 inpatient hospital acute 10-day length of stay cost sharing limit for an intermediate MOOP limit per § 422.100(f)(4)(vi) and (f)(6)(iv) (row C rounded per § 422.100(f)(6)(ii))	\$2,812.00

TABLE 20: CMS CALCULATIONS OF ILLUSTRATIVE CONTRACT YEAR 2024 INPATIENT HOSPITAL ACUTE 10-DAY LENGTH OF STAY SCENARIO COST SHARING LIMITS FOR THE MANDATORY AND LOWER MOOP TYPES USING CONTRACT YEAR 2023 MEDICARE FFS DATA PROJECTIONS (BASED ON 2017 – 2021 MEDICARE FFS DATA)

Row		Mandatory MOOP	Lower MOOP
Reference	Description	Type	Type
A	Projected Part A Deductible*		\$1,572.00
В	Projected Part B Professional Costs for a 10-day length of stay (with ESRD costs)*		\$955.00
С	Total estimated Medicare FFS cost sharing for a 10-day length of stay with ESRD costs (row A plus row B)		\$2,527.00
D	Allowable percentage of Medicare FFS estimated cost sharing by MOOP type per § 422.100(f)(4)(iv)	100%	125%
Е	Unrounded illustrative contract year 2024 cost sharing limit (row C multiplied by row D)	\$2,527.00	\$3,158.75
F	Rounded illustrative contract year 2024 cost sharing limit (row E rounded per § 422.100(f)(6)(ii)	\$2,527.00	\$3,159.00

^{*}These amounts are for illustrative purposes only and are the values for contract year 2023 from rows A and B in Table 18. CMS will use updated projected Part A deductible and Part B professional costs to calculate the final contract year 2024 inpatient hospital cost sharing limits.

TABLE 21: CMS CALCULATIONS OF ILLUSTRATIVE CONTRACT YEAR 2024 INPATIENT HOSPITAL ACUTE 10-DAY LENGTH OF STAY SCENARIO COST SHARING LIMIT FOR THE INTERMEDIATE MOOP TYPE USING CONTRACT YEAR 2023 MEDICARE FFS DATA PROJECTIONS (BASED ON 2017 – 2021 MEDICARE FFS DATA)

Row	D : 4:	Intermediate
Reference	Description	MOOP Type
A	Unrounded illustrative contract year 2024 inpatient hospital acute	\$2,527.00
	10-day length of stay scenario cost sharing limit for the	
	mandatary MOOP type per § 422.100(f)(4)(vi) (row E,	
	mandatory MOOP limit column in Table 20)	
В	Unrounded illustrative contract year 2024 inpatient hospital acute	\$3,158.75
	10-day length of stay scenario cost sharing limit for the lower	
	MOOP type per § 422.100(f)(4)(vi) (row E, lower MOOP limit	
	column in Table 20)	
C	Unrounded illustrative contract year 2024 cost sharing limit per §	\$2,842.88
	422.100(f)(4)(iv) (numeric midpoint between row A and row B)	
D	Rounded illustrative contract year 2024 inpatient hospital acute	\$2,843.00
	10-day length of stay cost sharing limit for an intermediate	
	MOOP limit per § 422.100(f)(4)(iv) (row C rounded per	
	§ 422.100(f)(6)(ii))	

As discussed in section II.A. of this FC, CMS will monitor the percentage of beneficiaries with diagnoses of ESRD enrolled in MA plans compared to Medicare FFS. If appropriate, we will consider future rulemaking to alter the methodology CMS uses to calculate MOOP and cost sharing limits if there are significant unforeseen impacts or negative consequences that need to be addressed. We would also consider whether additional changes would outweigh the interests of maintaining a settled methodology for calculating the MOOP and cost sharing limits and sufficiently protect enrollees from changes in cost sharing and benefits from 1 year to the next. In addition, as proposed and finalized, § 422.113(f)(6)(iv)(C) provides that CMS may also use patient utilization information from MA encounter data. In the February 2020 proposed rule we explained that CMS compared inpatient hospital utilization information from both Medicare FFS and MA encounter data to determine the specific length of stay scenarios for which we proposed to calculate cost sharing limits. As finalized, CMS may pursue future rulemaking to add, remove, or modify the length of stay scenarios applied to

inpatient hospital acute and psychiatric cost sharing limits based on comparisons of inpatient hospital utilization information from both Medicare FFS and MA encounter data.

d. Emergency/Post-Stabilization Services and Urgently Needed Services (§ 422.113(b)(2)(v) and (vi))

Comment: Comments were mixed for CMS's proposals (in section VI.B.3.b. of the February 2020 proposed rule) related to emergency/post-stabilization services. A commenter generally supported increasing the copayment limits and the differential in cost sharing tied to the types of MOOP limit for the "emergency/post-stabilization services" service category. This commenter noted this was an important service category to change as it would incentivize MA plans to offer lower MOOP limits and enrollees to use the appropriate level of care, such as physicians' offices or urgent care centers, and not overutilize the higher cost emergency room services.

A few other commenters opposed increasing the cost sharing limit for emergency/post-stabilization services. The commenters were concerned that increasing the cost sharing limit (and by extension, permitting increased cost sharing) would have the undesirable outcome of deterring beneficiaries from going to the emergency room when medically necessary, even when immediate medical care is truly needed, as many Medicare beneficiaries will simply be unable to afford the cost sharing. In reference to those concerns, the commenters requested CMS lower or maintain the contract year 2021 emergency/post-stabilization services cost sharing limits (\$120 for the lower, voluntary MOOP limit and \$90 for the mandatory MOOP limit). The commenters did not specifically address a cost sharing limit (or approach) for emergency/post-stabilization services for MA plans that establish an intermediate MOOP limit.

A commenter stated that CMS is unfairly penalizing Medicare beneficiaries who receive emergency services as CMS has increased the cost sharing limits for emergency services for the voluntary and mandatory MOOP limits by 60 percent and 20 percent respectively over the last several years. In addition, a commenter stated survey results from the Centers for Disease

Control and Prevention (CDC) show that only a small percentage of emergency department visits are avoidable.⁴⁸ This commenter noted that in many cases, Medicare beneficiaries cannot tell whether their condition is life-threatening or not and regardless of the final diagnosis, if the beneficiary reasonably believes that they have a medical emergency, they are entitled to go to the emergency department and be treated. Similarly, another commenter stated that while CMS has increased the cost sharing limits in various service categories year by year, such increases can be particularly harmful to beneficiaries in the emergency services context. This commenter explained that due to the age and vulnerability of the Medicare population, visits to the emergency department are necessary and not substitutes for primary care.

Response: We agree with the commenters that excessive cost sharing rates discriminate against enrollees who need those services. CMS has a long-standing interpretation that payment of less than 50 percent of the estimated total MA plan financial liability discriminates against enrollees who need those services. We understand emergency services, by nature, are typically associated with critical health care needs and we agree that it is important that enrollees do not face unexpected and unreasonable financial hardships in accessing needed health care services. In addition, section 1852(d)(3) of the Act and our existing regulation at § 422.113 are clear that the determination whether an emergency medical condition exists is based on the prudent layperson standard. Our proposal was not designed to discourage enrollees from seeking or receiving emergency services to address an emergency medical condition. Our proposed cost sharing standards for emergency and post-stabilization care services were to set the maximum out-of-pocket cost sharing amount that an MA plan may require an enrollee to pay for a visit to an emergency room, inclusive of any variability in the costs of services provided during the emergency visit. Enrollees who are not in need of emergency care typically have access to care with lower or no cost sharing. For example, urgent care, additional telehealth, or supplemental

⁴⁸ Centers for Disease Control and Prevention National Hospital Ambulatory Medical Care Survey: 2017 Emergency Department Summary Tables, available at: https://www.cdc.gov/nchs/data/nhamcs/web_tables/2017_ed web tables-508.pdf.

benefits for nursing hotlines or transportation related to medical services are often available to enrollees. For example, based on March 2021 plan data (excluding employer and D-SNPs) approximately 40.6 percent of contract year 2021 plans (reflecting 38.5 percent of total enrollment) offer a transportation supplemental benefit for medical purposes and approximately 65.0 percent offered a nursing hotline (reflecting 66.6 percent of total enrollment). We expect that these types of services assist with care coordination and support enrollees in accessing the most appropriate place of care for their condition. In addition, beneficiaries eligible for full Medicaid benefits and the Qualified Medicare Beneficiary (QMB) program generally would not pay Medicare cost sharing for emergency services in MA plans, including D-SNPs.

Our proposal based the dollar limits on the projected Medicare FFS median total allowed amount for emergency services (including visit and related procedure costs, \$755) using contract year 2021 Medicare FFS data projections that were based on the 2015-2019 Medicare FFS data available at the time of the February 2020 proposed rule. We reviewed both the projected median and average total allowed amount from the OACT when determining the methodology for setting cost sharing limits for this category. If we had proposed to base our methodology on the projected average total allowed Medicare FFS amount (\$998 including visit and related procedure costs), the highest allowable cost sharing for a plan that established a lower MOOP limit would have been \$200, \$50 higher than our proposal to use the projected median. However, we chose to use the projected median, which means that roughly half of Medicare beneficiaries in the Medicare FFS program were expected to incur cost sharing that was likely higher than these costs. Since the February 2020 proposed rule, updated contract year 2023 Medicare FFS data projections using Medicare FFS data from 2017 - 2021 increases the projected median and average total allowed amounts for emergency services (including visit and related procedure costs) to \$861 and \$1,106, respectively. The maximum cost sharing limits for emergency services are not being changed to reflect these updated projections because our proposal was to calculate specific dollar amounts for cost sharing limits for emergency and post-stabilization

services. But understanding the out-of-pocket costs experienced in the Medicare FFS program provides important context for the cost sharing limits that we are adopting in this FC.

As discussed in the February 2020 proposed rule, to calculate the proposed emergency and post-stabilization care services cost sharing limits for the mandatory and lower MOOP limits (Mandatory - \$115 and Lower - \$150), CMS took 15 percent and 20 percent of the projected median total allowed amount (\$755) respectively, rounded to the nearest whole \$5 increment. In addition, the proposed cost sharing limit for an intermediate MOOP limit (\$130) was calculated based on the numeric midpoint of the related cost sharing limits for MA plans with mandatary and lower MOOP limits, rounded to the nearest whole \$5 increment. We realized that using up to 20 percent of this projected Medicare FFS median total allowed amount to set an emergency cost sharing amount for an MA plan that establishes a lower MOOP limit would result in an increase of the MA cost sharing limit, compared to the prior contract year. However, the cost sharing standard we proposed at § 422.113(b)(2)(v) for MA plans that establish a lower MOOP limit is comparable to what a beneficiary in Medicare FFS would be required to pay for a similar trip to the emergency room after reaching the Part B deductible, based on 20 percent of Medicare FFS costs. Therefore, we do not believe that setting a cost sharing standard that is based on costs that are 15 percent (for the mandatory MOOP limit) and 20 percent (for the lower MOOP limit) of the median projected total cost for emergency services (including visit and related procedure costs) experienced in the Medicare FFS program is discriminatory. Nor do we believe utilizing the numeric midpoint of those limits to set a cost sharing limit for intermediate MOOP limit is discriminatory. We believe that basing the MA cost sharing limits for these services to the projected costs for beneficiaries in the Medicare FFS program reasonably addresses and balances our goals for adopting cost sharing limits overall.

We proposed to align the highest permissible cost sharing amount (which is available for MA plans that use the lower MOOP limit) with original Medicare, by allowing a maximum emergency services cost sharing limit permitted per visit of \$150, as an incentive for plans to

offer a lower MOOP limit, which is another important financial protection for beneficiaries. If the cost sharing limits for emergency services do not change from the current amounts to reflect more recent Medicare FFS data projections and trends, we expect that the limits will act as a disincentive for MA plans to offer lower MOOP amounts. For example, for contract year 2021 (based on March 2021 plan data) approximately 85 percent of MA and MA-PD plans (excluding D-SNPs) established the highest allowable cost sharing for this service category based on the type of MOOP limit, suggesting that these upper limits may not fully reflect the costs MA organizations are experiencing to cover emergency services for enrollees. Conversely, while increasing flexibility in cost sharing standards may provide an incentive for plans to offer lower MOOP limits, we deliberately did not use percentages higher than 20 percent because we believe it is important to align with the coinsurance percentage that applies to most original Medicare Part B services. Therefore, we continue to believe that the dollar figures we proposed (\$115, \$130, and \$150) as the cost sharing limits for MA plans that use the mandatory, intermediate or lower MOOP limit are the appropriate final cost sharing limits to adopt for emergency services.

The cost sharing limits proposed at § 422.113 are reasonably close to emergency room copayment levels for employer and Qualified Health Plans. For example, the Kaiser Family Foundation (KFF) found that the majority of covered workers either have a coinsurance or copayment for an emergency room visit with the average coinsurance rate of 20 percent and the average copayment of \$180 based on a 2017 employer health benefits survey. ⁴⁹ The annual employer health benefits survey reports since the 2017 survey from KFF have not updated the average emergency room cost sharing rates at the time of writing this FC but are available online ⁵⁰. In addition, utilizing 2015 data from the Exchanges, KFF found that the average Qualified Health Plan copayment ranged from \$155 to \$318 and the average coinsurance ranged

⁴⁹ Kaiser Family Foundation. 2017 Employer Health Benefits Survey – Section 7: Employee Cost Sharing. Published September 19, 2017. Retrieved from https://www.kff.org/report-section/ehbs-2017-section-7-employee-cost-sharing/

⁵⁰ Kaiser Family Foundation. Employer Health Benefits Annual Survey Archives. Published November 10, 2021. Retrieved from: https://www.kff.org/health-costs/report/employer-health-benefits-annual-survey-archives/.

from 20 percent to 32 percent based on the type of plan (bronze, silver, gold, or platinum).⁵¹ This report was last updated using 2016 data from the Exchanges, and KFF found that the average Qualified Health Plan copayment increased to \$171 - \$430 and the average coinsurance changed to 19 percent to 34 percent based on the type of plan (bronze, silver, gold, or platinum).⁵² While setting cost sharing limits based on 15 and 20 percent of Medicare FFS costs in itself is not discriminatory or out of line with the market, we acknowledge that a substantial change in cost sharing limits from one year to the next may produce disruption for enrollees. As discussed in sections II.B.5.b. and e. of this FC, CMS is making several changes in implementing the proposed cost sharing policies addressed in this FC to minimize potential disruption in implementing the changes in cost sharing proposed in this rulemaking. For example, we are using a 4-year transition to reach the proposed range of cost sharing limits for professional services. As discussed in section V.H.2. of this FC, CMS also considered several alternatives to implementing the proposed cost sharing limits for emergency services (renamed for clarity as discussed in a following response to comment in this section) to minimize potential enrollee disruption. After consideration of those alternatives, we believe a multiyear transition to the proposed cost sharing limits for emergency services would be beneficial and responsive to comments. Applying a transition to the new copayment limits (for emergency services) and use of maximum coinsurance percentages and actuarially equivalent copayment amounts (for urgently needed services) should be helpful as it will: (1) smooth the possible changes in cost sharing for these service categories over several years to avoid potentially disruptive increases in costs for enrollees; and (2) provide MA organizations several years of advance notice of what the specific cost sharing limits will be (for emergency services) and what the coinsurance limits will be (for urgently needy services) to consider whether it makes sense for their plans to use the

⁵¹ Kaiser Family Foundation. The Cost of Care with Marketplace Coverage. Published February 11, 2015. Retrieved from https://www.kff.org/health-costs/issue-brief/the-cost-of-care-with-marketplace-coverage/

⁵² Kaiser Family Foundation. Patient Cost-Sharing in Marketplace Plans, 2016. Published November 13, 2015. Retrieved from: https://www.kff.org/health-costs/issue-brief/patient-cost-sharing-in-marketplace-plans-2016/.

maximum permitted cost sharing when planning their bid designs. As a result, we are modifying § 422.113(b)(2)(v) to apply a 4-year transition to reach the proposed cost sharing limits based on the type of MOOP limit for emergency services. With regard to urgently needed services, where we proposed and are finalizing that the cost sharing limits for in-network basic benefits that are professional services apply to MA plans, the transition adopted in § 422.100(f)(6)(iii) and (f)(8) will also apply. This applies regardless whether the urgently needed services are furnished innetwork or out-of-network because § 422.113 requires MA plans to cover urgently needed services without regard to whether the services are furnished by an in-network provider or prior authorization. As a result, we are adopting a transition for the cost sharing limits proposed for both emergency services and urgently needed services. We believe this approach to implement these cost sharing proposals in §§ 422.100(f)(6)(iii), (j)(1), and 422.113(b)(2) through a 4-year transition will support a consistent and streamlined approach in updating MOOP and cost sharing limits.

We developed the transition schedule finalized in § 422.113(b)(2)(v) by taking the difference between the proposed cost sharing amounts for emergency services and the current (contract year 2022) cost sharing limits and incorporating 25 percent of the difference each year over a 4-year period and applying the rounding rules. In addition, contract year 2023 will be the first year CMS sets an intermediate MOOP limit. For purposes of calculating the transitional cost sharing limits for the intermediate MOOP limit, CMS used the numeric midpoint between the transitional cost sharing limits for the mandatory and lower MOOP limits before application of the rounding rules, then applied the rounding rules to that midpoint amount. This is consistent with our proposal to set maximum cost sharing limits for MA plans with an intermediate MOOP limit based on the numeric midpoint of the related cost sharing limits for MA plans with mandatory and lower MOOP limits, rounded to the nearest whole \$5 increment. The calculations CMS completed to reach the final contract year 2023 emergency services cost sharing limits are available in Table 22 and 23. Similar calculations as shown in Tables 22 and 23 were completed

to reach the final cost sharing limits for the following years of the transition, contract years 2024 through 2026. In summary, applying this transition and the rounding rules in § 422.100(f)(6)(ii) results in the emergency services cost sharing limits summarized in Table 24 for contract year 2023 and future years, which is what we are finalizing in § 422.113(b)(2)(v). Specifically, emergency services cost sharing limits will be transitioned to the amounts proposed for contract year 2026 and maintained for subsequent years. CMS modified the cost sharing limits proposed in paragraphs § 422.113(b)(2)(v)(1), (2), and (3) and is finalizing a new paragraph (b)(2)(v)(4) to set the cost sharing limits as shown in Table 24. The final contract year 2023 emergency services cost sharing limits are also summarized in Table 28 which updates the illustrative cost sharing limits from the February 2020 proposed rule's Table 5 (Illustrative Contract Year 2022 In-Network Service Category Cost Sharing Limits) for comparison purposes.

TABLE 22: CMS CALCULATIONS OF FINAL CONTRACT YEAR 2023 EMERGENCY SERVICES COST SHARING LIMITS FOR THE MANDATORY AND LOWER MOOP TYPES (§ 422.113(b)(2)(v))

Row		Lower	Mandatory
Reference	Description	MOOP	MOOP
A	Contract year 2022 emergency care/post	\$120.00	\$90.00
	stabilization care cost sharing limits		
В	Proposed emergency care/post stabilization care cost	\$150.00	\$115.00
	sharing limits		
С	Total Difference (row A minus row B)	\$30.00	\$25.00
D	25% of the Difference (row C multiplied by 0.25)	\$7.50	\$6.25
Е	Unrounded contract year 2023 emergency	\$127.50	\$96.25
	services cost sharing limits (row A plus row D)		
F	Rounded contract year 2023 emergency services	\$125.00	\$95.00
	cost sharing limits (row E rounded per		
	§ 422.100(f)(6)(ii))		

TABLE 23: CMS CALCULATIONS OF THE FINAL CONTRACT YEAR 2023 EMERGENCY SERVICES COST SHARING LIMIT FOR THE INTERMEDIATE MOOP TYPE (§ 422.113(b)(2)(v))

Row Reference	Description	Intermediate MOOP
A	Unrounded contract year 2023 emergency services cost sharing limit for the lower MOOP limit (value in row E for the lower MOOP column from Table 22)	\$127.50
В	Unrounded contract year 2023 emergency services cost sharing limit for the mandatory MOOP limit (value in row E for the mandatory MOOP column from Table 22)	\$96.25
С	Unrounded contract year 2023 emergency services cost sharing limit for the intermediate MOOP limit (numeric midpoint between row A and row B)	\$111.88
D	Rounded contract year 2023 emergency services cost sharing limit for the intermediate MOOP limit (row C rounded per § 422.100(f)(6)(ii))	\$110.00

TABLE 24: FINAL MULTIYEAR TRANSITION FOR EMERGENCY SERVICES COST SHARING LIMITS BASED ON THE MOOP TYPE (§ 422.113(b)(2)(v))

MOOP Level	2022*	2023	2024	2025	2026 and Future Years
Lower (Previously "voluntary")	\$120	\$125	\$135	\$140	\$150
Intermediate	N/A	\$110	\$120	\$125	\$130
Mandatory	\$90	\$95	\$100	\$110	\$115

^{*}Cost sharing limits for contract year 2022 provided for comparison purposes.

In setting a 4-year transition to the proposed cost sharing limits, CMS is attempting to strike a balance between the needs of beneficiaries to seek emergency care and plan costs associated with the variety and expense of services included in the cost sharing limit. The dollar amounts for emergency services represent the maximum cost sharing permitted per visit (including related procedure costs) and are not subject to plan level deductibles or network restrictions. CMS will continue to track Medicare FFS cost trends for emergency services and may consider future rulemaking to update these cost sharing limits, if appropriate. For example, we will continue to review the projected average and median Medicare FFS allowed amounts from the OACT annually, consult with the OACT on whether any applicable cost trends are expected to be consistent for future contract years, and consider how market competition or payment policies may affect or necessitate changes to the methodology CMS used to calculate cost sharing limits proposed and finalized here.

We are also finalizing the proposal, at § 422.113(b)(2)(vi), that cost sharing for urgently needed services must not exceed the limits on cost sharing that are specified for professional services in § 422.100(f)(6)(iii). This means that cost sharing limits for urgently needed services may vary with the type of MOOP limit. Further, as with professional services, the cost sharing for urgently needed services may not exceed a set coinsurance percentage or an actuarially equivalent copayment value, and the values for copayment limits may be calculated by CMS applying the methodology in this FC or by the MA organization based on the estimated total MA plan financial liability for that contract year if CMS does not calculate the copayment limit for

the specific service or service category. In addition, our proposed in-network cost sharing standards for urgently needed services represent the maximum out-of-pocket cost sharing amount that an MA plan may require an enrollee to pay for these services, inclusive of any variability in the costs provided during the visit. Specifically, CMS may calculate copayment limits for urgently needed services based on § 422.100(f)(6)(iii) (and new paragraph (f)(8)(i) during the transition to actuarially equivalent copayment limits). A more complete discussion related to the requirement for cost sharing for professional services, the range of permissible cost sharing, and the transition to actuarially equivalent copayment limits is available in section II.B.5.b. of this FC.

We are finalizing our proposals related to emergency services and urgently needed services generally as proposed, with 4-year transitions to reach the proposed cost sharing limits. We are not finalizing the proposal to consolidate the cost sharing limits for emergency and post-stabilization services (as discussed in a following response to comment in this section).

Comment: A commenter was concerned that increasing the cost sharing limits for emergency/post-stabilization services (and by extension, permitting increased cost sharing amounts) may further burden hospitals with uncollectable bad debts. The commenter believed this proposed increase in cost sharing would burden hospitals because: (1) many Medicare beneficiaries will be unable to afford the cost sharing; (2) MA organizations are not required to pass along to hospitals (or other providers) payments of uncollected cost sharing (that is, bad debt) that are built into the capitated payments that MA organizations receive from CMS; and (3) MA organizations have considerable bargaining power over their network providers — particularly as the payer market has consolidated nationwide — which makes it unrealistic to expect an MA organization would agree to pass on these payments to providers. As a comparison, this commenter noted that the traditional Medicare program accounts for beneficiaries not being able to afford emergency room cost sharing and reimburses providers for uncollected cost sharing, such as copayments and co-insurance. In addition, the commenter

noted that while it may be suggested that this is a matter for MA organizations and providers to resolve through their private agreements, it is unclear why providers should not be reimbursed for uncollected cost sharing amounts solely because the patient is enrolled in an MA plan instead of Medicare FFS. Due to these factors, the commenter requested CMS require MA organizations reimburse providers for uncollected cost sharing from beneficiaries.

Response: To clarify information in the comment, under Medicare FFS, CMS permits inclusion of uncollectible Medicare deductible and coinsurance amounts in allowable costs for certain providers (42 CFR § 413.89) and reimburses these amounts subject to the limitations set forth in § 413.89(h), however this reimbursement does not apply to MA plans. We agree with the commenter that currently MA organizations, hospitals, and provider groups negotiate contractual terms, including payment arrangements, to meet the needs of each party, including how uncollected cost sharing is handled. Allowing for private organizations to negotiate with one another to provide health care services for beneficiaries is core to the MA program. We believe the MA program affords flexibility and allows market competition to provide plan options that meet the needs of beneficiaries. Further, and perhaps most importantly, section 1854(a)(6)(B)(iii) of the Act and § 422.256(a)(2)(ii) prohibit CMS from requiring a particular price structure to be used between MA organizations and their contracted providers; we view this issue regarding payment by the MA organization of certain amounts to a contracted provider to be within the scope of this prohibition. In addition, the commenter's overarching request that CMS require MA organizations to reimburse providers for uncollected cost sharing from beneficiaries (for all cost sharing, not limited to emergency and post-stabilization care services) is out-of-scope of our proposal. We proposed to adopt specific cost sharing limits for this service category based on a particular methodology.

<u>Comment:</u> A few commenters supported CMS creating a single cost sharing limit for emergency/post-stabilization services. A commenter that supported a single cost sharing limit (using a specific dollar amount) for emergency/post-stabilization services appreciated the greater

transparency the February 2020 proposed rule provided in how CMS establishes these cost sharing limits and agreed that it can be difficult for enrollees to differentiate emergency services from post-stabilization services. Another commenter requested CMS confirm and provide clarification that the emergency/post-stabilization services category will remain consistent with the current industry practice regarding which services are included (services provided while in the emergency department) and which are excluded (inpatient acute care services). This commenter noted that if inpatient services were included this would be contrary to and a drastic change from current industry practice.

Response: We thank the commenters for their feedback on our proposal to create a single cost sharing limit for emergency and post-stabilization care services. Currently, § 422.113(b)(1)(ii) and (c)(1) defines the terms "emergency services" and "post-stabilization care services." "Emergency services," which is also defined in section 1852(d)(3) of the Act, means, with respect to an individual enrolled with an MA organization, covered inpatient and outpatient services that are furnished by a provider qualified to furnish emergency services and needed to evaluate or stabilize an emergency medical condition. "Post-stabilization care services" means covered services related to an emergency medical condition, that are provided after an enrollee is stabilized in order to maintain the stabilized condition, or, under the circumstances described in § 422.113(c)(2)(iii), to improve or resolve the enrollee's condition. We also direct readers to section 1852 of the Act and § 422.113(c) which require MA organizations to cover post-stabilization care services in specified circumstances. Although poststabilization may encompass a wide variety of services, we proposed to include post-stabilization care services with the emergency services category in order to reflect the services the enrollee receives immediately following stabilization in the emergency department. We agree with the commenter that including post-stabilization care services received as an admitted inpatient in the hospital as subject to the dollar limits proposed in § 422.113(b)(2)(v) would be a significant change from current industry practice. CMS has not and does not intend to include inpatient

acute care services in these dollar limits because we proposed (and finalized as discussed in section II.B.5.c. of this FC) separate cost sharing limits for inpatient hospital acute and psychiatric length of stays in § 422.100(f)(6)(iv). MA plans must limit charges to enrollees for post-stabilization care services to an amount no greater than what the organization would charge the enrollee if he or she had obtained the services through the MA organization and for purposes of cost sharing, post-stabilization care services begin upon inpatient admission under § 422.113(c)(2)(iv). Limiting post-stabilization care services – and thus limiting the cost sharing limit for those services – to services that begin upon inpatient admission continues a policy in place since at least 2005 (70 FR 4632–33) and we did not propose to revise § 422.113(c)(2)(iv). As a result, we are finalizing the cost sharing limits proposed for emergency services under § 422.113(b)(2)(v) without reference to post-stabilization care services.

CMS described how post-stabilization may encompass a wide variety of services but is used in § 422.113 to reflect the services the enrollee receives immediately following stabilization in the emergency department in the CY 2019 Final Call Letter (issued April 2, 2018). This approach separates post-stabilization care services received as an admitted inpatient from emergency services and is also consistent with CMS's policy in the "Medicare Program; Establishment of the Medicare Advantage Program; Final Rule" published January 28, 2005 (referred to as the January 2005 final rule). For example, comments summarized in the January 2005 final rule supported CMS's clarification that the cost sharing limit for emergency services applied only to emergency department services and the notion that once an MA enrollee is admitted to a hospital, normal hospital cost sharing levels apply, even if the inpatient admission originates in the emergency department. As such, we clarify and reiterate that while the definition of emergency services references covered inpatient and outpatient services, CMS is not including post-stabilization inpatient acute care services for purposes of setting the cost sharing limits for emergency services in paragraph (b)(2)(v).

This distinction between services furnished in an emergency department from inpatient services after admission was used in our development of the cost sharing limits we are finalizing in § 422.113(b)(2)(v) for emergency services. As discussed previously in this section and in the February 2020 proposed rule, we used the projected median total allowed amount for emergency services (including visit and related procedure costs), based on the Medicare FFS data projections available at the time of the February 2020 proposed rule. These data were based on a sample of approximately 10,000 beneficiaries, excluding those that were admitted from the emergency room to the hospital as an inpatient within 3 days. In those cases where the beneficiary was admitted to the hospital, the emergency room or outpatient department services are paid for as part of the inpatient stay based on Medicare's "3-day payment window" for inpatient admissions. As a result, the projected median total allowed amount for emergency services used to calculate the proposed dollar limits did not need to be recalculated to remove any post-stabilization care costs related to services beneficiaries received once admitted to the hospital as an inpatient. Likewise, our proposed (and finalized) methodology to calculate inpatient hospital acute and psychiatric cost sharing limits did not require modification because post-stabilization care costs received as an inpatient are included in the projected Part B costs.

We are finalizing the proposed provisions regarding cost sharing for emergency services with modifications to apply a 4-year transition to reach the proposed cost sharing limits, remove post-stabilization care services language in \S 422.113(b)(2)(v), and complete non-substantive formatting changes to ensure consistency in the regulation text in paragraphs (b)(2)(v)(1), (2), (3), and (4). We are not revising \S 422.113(c)(2)(iv) and therefore continue current policy that for purposes of cost sharing, post-stabilization care services begin upon inpatient admission; the cost sharing limits finalized at \S 422.112(c)(2)(v) do not apply to post-stabilization inpatient acute care services. We note here that as ambulance services are not emergency or post-stabilization care services, there may be a separate cost sharing amount required for ambulance services. As discussed in section II.B.5.b. of this FC, ambulance services are not professional

services for which cost sharing is set under § 422.100(f)(6)(iii) but are subject to the cost sharing limits set under § 422.100(f)(6)(i).

e. Services No Greater Than Original Medicare (§ 422.100(j)(1))

Comment: As discussed in other comment summaries in section II.B.5. of this FC and in this section, some commenters suggested that the proposed cost sharing limits in general and for specific service categories (including those subject to the statutory requirements in section 1852 (1)(B)(iv) of the Act, such as dialysis services) are discriminatory, pose too significant increases from the prior contract year, and would substantially discourage enrollment by beneficiaries who require those services. In addition, as referenced in other comment summaries in section II.A.4. and II.B.5. of this FC, a few commenters had concerns that the proposed changes to the MOOP and cost sharing standards within one year would negatively affect a plan's ability to meet the TBC standard. While these commenters' concerns regarding TBC are also relevant to the cost sharing proposals, the commenters' concerns regarding TBC are also relevant to the cost sharing proposals at § 422.100(j)(1) as they will also impact the TBC standard.

Response: We appreciate the feedback from commenters and address specific service category concerns in other responses to comment in section II.B.5. of this FC. Here, we address the general changes CMS is incorporating to address commenter concerns about potentially disruptive or discriminatory increases to cost sharing limits within one year as they relate to service categories subject to § 422.100(j)(1). As proposed and finalized paragraph (j)(1) requires MA plans to have cost sharing that does not exceed cost sharing in original Medicare for specified service categories. In section III. of this FC, CMS is soliciting comment for future additions to the cost sharing regulations as well.

As referenced in section II.B.5.a. of this FC, CMS may calculate copayment limits for any category of in-network professional services for 2023 and future years and our intention is to calculate copayment limits using the methodology in this FC for as many service categories as possible, including those service categories that are subject to § 422.100(j)(1). We believe

calculating and issuing limits on cost sharing for covered services and ensuring MA organizations comply with these limits are important ways to ensure that the cost sharing aspect of a plan design does not discriminate against or discourage enrollment in an MA plan by beneficiaries who have high health care needs. CMS issued annual limits on cost sharing for covered services and guidance addressing discriminatory cost sharing, as applied to specific benefits and to categories of benefits, in the annual Call Letter (issue dates prior to 2020⁵³) and in bidding instructions. In addition, Chapter 4 of the Medicare Managed Care Manual (MMCM)⁵⁴ has contained long-standing polices regarding discriminatory cost sharing based on the requirements under paragraph § 422.100(f). The review of bids can be streamlined and simplified if CMS has specific copayment limits to apply as well as coinsurance limits for the service categories in the bid. While the coinsurance limits are also applicable, we believe that copayments are more readily understood by beneficiaries and provide beneficiaries with more definite means to predict their out-of-pocket costs when selecting among Medicare coverage options. Section 1852(a)(1)(B) of the Act specifies that MA plans may not charge higher cost sharing than is charged under original Medicare for certain benefits and provides authority for CMS to add other benefits for which enrollees will have this protection. CMS believes that calculating copayment limits at actuarially equivalent values to cost sharing required under original Medicare (based on the most recent Medicare FFS data projections) for these services will protect enrollees. This approach provides a clearer standard for both types of cost sharing (coinsurance and copayments). We are finalizing paragraph (i)(1) with some reorganization and edits for clarification and additional policies related to the policy. In order to better address this in the regulation and accommodate other changes as discussed in this response, proposed paragraphs (i)(1)(i) - (v) are re-designated as paragraphs (i)(1)(i)(A) - (E) in this FC.

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⁵³ See the HPMS memorandum titled "Final Contract Year 2021 Part C Benefits Review and Evaluation," issued April 8, 2020, for information on MOOP and cost sharing limits for contract year 2021 and the HPMS memorandum titled "Final Contract Year 2022 Part C Benefits Review and Evaluation," issued May 20, 2021, for information on MOOP and cost sharing limits for contract year 2022.

⁵⁴ Chapter 4 of the MMMCM can be accessed at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c04.pdf

We are finalizing $\S 422.100(j)(1)$ and (j)(1)(i) with the substance of proposed paragraph (i)(1) that in-network cost sharing established by an MA plan may not exceed the cost sharing required under original Medicare for the specific basic benefits and categories of basic benefits identified in paragraphs (j)(1)(i)(A) through (F). The revisions in this FC clarify that this requirement applies to coinsurance and copayments used by MA plans, that copayment limits are subject to the rounding rules finalizing in § 422.100(f)(6)(ii), and that when CMS calculates a copayment limit under paragraph (j)(1)(ii), copayments used by MA plans must not exceed those copayment limits. Copayments used by MA plans for the benefits listed in paragraph (j)(1) would generally be calculated at values that are actuarially equivalent to the cost sharing used in original Medicare, subject to limits on the increase in copayment levels when CMS calculates the copayment limit during a 4-year transition period. The transition period for the copayments for the service categories specified in paragraph (j)(1)(i) is the same as the transition period finalized for in-network basic benefits that are professional services specified in § 422.100(f)(6)(iii) and is codified at § 422.100(f)(8) (as discussed in more detail in section II.B.5.b. of this FC and subsequently in this response). We reiterate that MA plans always have the option to use either coinsurance or copayments in establishing the cost sharing obligations for their enrollees. The maximum coinsurance percentage permitted as cost sharing for the service categories listed in paragraph (j)(1)(i) regardless of MOOP type (excluding skilled nursing care, home health, and DME service categories) is 20 percent, which is the coinsurance used in original Medicare for those benefits.

We are finalizing the rules for calculating the copayment limits applicable to these services in § 422.100(j)(1)(ii). Section 422.100(j)(1)(i) requires that any copayment for these benefits used by an MA plan must not exceed the actuarially equivalent value calculated using the rules in paragraph (j)(1)(ii). When CMS calculates the copayment limit, we will follow the methodology in paragraphs (f)(7) and (8), as discussed in section II.B.5.a. of this FC. In brief, this means that CMS will use Medicare FFS data projections (as defined in § 422.100(f)(4)(i))

for the applicable year and service category and, where consistent with paragraph (f)(7)(ii), MA encounter data. In addition, CMS will calculate copayment limits to be actuarially equivalent to the coinsurance required under original Medicare for the specified benefits and service categories in paragraph (j)(1), subject to the annual cap on increases to copayment limits calculated by CMS from year to year during the transition period in paragraph (f)(8). As with all of the projections and calculations performed under this FC, the final regulation requires that generally accepted actuarial principles and practices will be followed. If CMS does not calculate a copayment limit for a service category listed in paragraph (j)(1) and an MA plan wishes to use a copayment, it must establish a copayment that is equal to or less than an actuarially equivalent value to cost sharing required under original Medicare. Paragraph (j)(1)(ii) provides that an MA plan may use either the average Medicare FFS allowed amount in the plan's service area or the estimated total MA plan financial liability for that benefit for that contract year in calculating the actuarially equivalent value. Allowing MA organizations to use the estimated total MA plan financial liability for that contract year is consistent with longstanding practice for the supporting documentation process CMS has used when we have not calculated a copayment limit but a coinsurance limit does apply, as discussed in section II.B.5.a. of this FC. We are finalizing the flexibility for MA plans to also use the average Medicare FFS allowed amount as that data would clearly reflect cost sharing under original Medicare for the benefit and service area and may reduce burden for MA plans. It is not necessary for an MA organization to use one data source over the other. Regardless of whether the MA organization uses the average Medicare FFS allowed amount for the benefit and service area or the estimated total MA plan financial liability for that contract year to calculate actuarially equivalent copayments, the calculations would be calculated at the plan level (or segment, if applicable).

Following the finalized methodology set through this FC, CMS calculated copayment limits for most of the service categories listed in § 422.100(j)(1) for contract year 2023. CMS does not expect that calculating copayment limits for the same service categories subject to

paragraph (j)(1) as we have traditionally done in past years, will increase the burden of complying with these standards for MA organizations. The PBP software includes validations to prevent an MA organization from entering cost sharing for a particular service category that is above the cost sharing limit calculated and issued by CMS. This process will be maintained for contract year 2023 using the final cost sharing limits in Table 28. In addition, CMS expects to maintain this PBP validation in future years. This approach will help manage the administrative burden in developing and reviewing plan bids because without a copayment limit calculated by CMS, each plan bid would need to be prepared and evaluated in relation to either the average Medicare FFS allowed amount for the plan service area or the estimated total MA plan financial liability for the benefit for that contract year. In the absence of specific copayment limits, MA organizations may need to prepare supporting documentation for the cost sharing established. A more detailed discussion about how MA organizations may approach preparing supporting documentation for service categories subject to paragraph (j)(1) is available in section II.B.5.a. of this FC.

Our intention in this rulemaking is to set and codify a body of cost sharing standards that by themselves, and in combination with one another, guard against discriminatory plan designs by limiting the amount of cost sharing and out-of-pocket costs that MA plans may impose on enrollees for basic benefits. Since contract year 2011, we have calculated cost sharing limits for this purpose, but codifying the methodology will provide additional transparency for stakeholders and stability for the MA program. This FC will result in changes from the cost sharing limits that apply for contract year 2022, primarily for copayment limits, for many service categories. As discussed in section II.B.5.b. and d. of this FC in relation to copayment limit changes for professional services and emergency services, we agree with commenters that substantive changes to copayment limits should be implemented over several years to reduce disruption in the market and for enrollees. Use of a transition period to smooth these changes also aligns with our approach in several places in the February 2020 proposed rule, such as the

multiyear incorporation of ESRD costs into the methodology that CMS uses to calculate MOOP and inpatient hospital cost sharing limits. Further, we acknowledge the concerns from commenters regarding changes resulting from this FC impacting the TBC standard. We expect the changes we are finalizing here (including a transitional period to update copayment limits for service categories subject to § 422.100(j)(1)) combined with the TBC evaluation will ensure that enrollees who continue enrollment in the same plan from one year to the next are not exposed to significant cost increases (or benefit decreases) in one year while, at the same time, ensure that MA organizations do not face unreasonable challenges to satisfy the TBC evaluation.

Table 28 includes final contract year 2023 cost sharing limits for most of the service categories that we proposed to add to § 422.100(j). The copayment values in Table 28 also reflect the requirements in new § 422.100(f)(7) and (8). As discussed in section II.B.5.b. of this FC, the copayment limits set for some service categories in past years do not reflect values that are actuarially equivalent to the applicable coinsurance levels, including those service categories subject to paragraph (i)(1) where the comparison is to 20 percent coinsurance used in original Medicare. Rather, some of the contract year 2022 copayment limit amounts have been in place without change for a number of years and were originally set to strike a balance between limiting beneficiary out-of-pocket costs and the potential impact to plan design and costs. The overarching goal of these copayment limits was to ensure beneficiary access to affordable and sustainable benefit packages rather than to be precisely tied to cost sharing in original Medicare each year. Our proposed methodology to calculate copayment limits based on actuarially equivalent values to the coinsurance limit, in effect, would recalibrate copayment limits within 1 year by using the methodology finalized here (while coinsurance limits for the service categories subject to paragraph (j)(1) remain consistent with longstanding practice by being set at the cost sharing required under original Medicare). Following this methodology, some of the illustrative copayment limits for professional services provided in Table 5 (Illustrative Contract Year 2022 In-Network Service Category Cost Sharing Limits) in the February 2020 proposed

rule reflected potentially substantial increases from the prior contract year. Table 5 from the February 2020 proposed rule illustrated that the copayment limits were projected to increase, despite decreasing the coinsurance limits based on the MOOP type for the professional service categories from past years, as a result of using the most recent Medicare FFS data available to calculate actuarially equivalent copayment values at the time of the February 2020 proposed rule. Several commenters submitted general concerns about cost sharing increases, including for particular service categories. While illustrative copayment limits that were actuarially equivalent to the cost sharing under original Medicare for all of the services categories subject to paragraph (j)(1) were not provided in the February 2020 proposed rule (rather, only coinsurance limits were provided in Table 5), based on the comments received, and in relation to the "Part B drugs — Other" service category (as discussed in section II.B.5.f. of this FC and a subsequent response to comment in this section), we believe feedback from the commenters was clear that enrollees should be protected from potentially significant increases in copayment amounts, especially within a one year timeframe.

Using on contract year 2023 Medicare FFS data projections (based on Medicare FFS data from 2017 – 2021), the actuarially equivalent values to 20 percent coinsurance for certain service categories subject to § 422.100(j)(1) would produce significant increases to the copayment limits compared to those set for contract year 2022. For example, the contract year 2023 projected total median cost per session for the "Part B – chemotherapy/radiation drugs" service category equals \$1,397.00 and the total weighted average cost per session equals \$4,038.00 based on contract year 2023 Medicare FFS data projections. Using these projections, an actuarially equivalent copayment limit to the 20 percent coinsurance limit would be \$280 (based on the total median cost per session) or \$810 (based on the total weighted average cost per session), after applying the rounding rules in § 422.100(f)(6)(ii). In comparison, the contract year 2022 copayment limit was \$75 for the "Part B – chemotherapy/radiation drugs" service category. As a result, calculating a copayment limit at an actuarially equivalent dollar amount to 20 percent of

\$1,397.00 or \$4,038.00 in contract year 2023 would be a substantial increase (from \$75 in contract year 2022 to \$280 or \$810 in contract year 2023 based on the projected median and average per session costs, respectively) and would not adequately protect enrollees from potentially disruptive changes compared to the prior contract year. However, not updating the copayment limits to reflect the most recent actuarially equivalent values would not be consistent with our proposal, would result in copayment limits that require MA plans to have copayments that are significantly less than the cost sharing in original Medicare when section 1852(a)(1)(B) of the Act imposes the cost sharing in original Medicare as the maximum permitted for an MA plan, and would not address the rapid scientific advancements in cancer treatments and the costs MA organizations are expected to incur in providing these services for MA enrollees. For example, the OACT is projecting the utilization of chimeric antigen receptor T cells (CAR-T) therapy and other expensive immunological treatments will increase and substantively impact aggregate costs for the "Part B drug – chemotherapy/radiation drugs" service category starting in 2022. A similar increase in expensive drugs is projected for the Medicare FFS data that CMS may use for the copayment limits for the "Part B drugs – Other" service category (as discussed in a subsequent response to comment in this section and shown in Table 25B). As discussed in the February 2020 proposed rule, enrollees generally find copayments more predictable and less confusing than coinsurance⁵⁵. As discussed in a subsequent response to comment in this section, currently, the vast majority of MA plans have designed their "Part B drugs – other" benefit with cost sharing greater than zero and use coinsurance rather than a copayment. For contract year 2021 (based on March 2021 plan data) approximately 2 percent of MA and MA-PD plans (excluding employer, D-SNPs, and MSA plans) established a copayment for the "Part B drugs – other" service category (\$50 or greater than zero), suggesting that the upper copayment limits for

⁵⁵ Loewenstein G, Friedman JY, McGill B, Ahmad S, Linck S, Sinkula S, Beshears J, J.Choi J, Kolstad J, Laibson D, Madrian BC, List JA, Volpp KG. "Consumers' misunderstanding of health insurance". Journal of Health Economics 2013;32(5):850-862. Retrieved from: https://scholar.harvard.edu/laibson/publications/consumers-misunderstanding-health-insurance

contract year 2021 (which were maintained for contract year 2022) may not fully reflect the costs MA organizations are experiencing to cover this benefit for enrollees or the out-of-pocket payments required from most MA enrollees. We believe recalibrating copayment limits to be actuarially equivalent to the coinsurance percentage used for the benefits listed in paragraph (j)(1) may incentivize MA organizations to design benefit packages using copayment structures for more service categories than in prior years.

Based on the potentially disruptive changes from updating contract year 2022 copayment limits to actuarially equivalent values for service categories subject to § 422.100(j)(1) for contract year 2023, concerns from commenters regarding discriminatory benefit designs for service categories subject to paragraph (j)(1) (such as dialysis services as discussed in a subsequent response to comment in this section), and the variability of provider contracting arrangements among MA organizations, we considered alternatives to ensure that copayment limits would be appropriately updated to reflect the most recent Medicare FFS data projections while also limiting the amount of change that could be incorporated within one year to protect enrollees. The alternatives we considered are discussed in section V.H. of this FC. After consideration of those alternatives, we believe a multiyear transition to actuarially equivalent copayment limits based on the most recent Medicare FFS data projections for service categories subject to paragraph (i)(1) would be beneficial and responsive to comments. Specifically, applying a multiyear transition to actuarially equivalent copayments during a period of potential disruption should be helpful as it will facilitate incremental changes and provide advance notice for MA organizations to consider in planning their bid designs.

As discussed in section II.B.5.b. of this FC, we are finalizing at § 422.100(f)(8) a provision that will cap the amount of change in copayment limits from year to year. That constraint permits a gradual transition from the copayment limits that are in place for contract year 2022 to copayment limits that are calculated using the actuarially equivalent value to cost sharing under original Medicare. If CMS calculates copayment limits for the services listed in

§ 422.100(j)(1), we will apply new paragraph (f)(8) to those copayment limits for the transition period of 2023 through 2026. This is explicit in § 422.100(j)(1)(ii) as finalized here. This copayment transition is discussed in detail in section II.B.5.b. of this FC as it is being operationalized in the same manner for service categories subject to paragraph (f)(6)(iii). The only substantive difference between service categories subject to paragraph (f)(6)(iii) and (j)(1) is the applicable coinsurance limit(s) used to calculate actuarially equivalent values. Under paragraph (j)(1), most of the service categories (excluding skilled nursing care, home health, and DME) are subject to a 20 percent coinsurance limit regardless of the MOOP type which is the cost sharing beneficiaries must pay under original Medicare; our current guidance on cost sharing limits for those services where MA plans cannot exceed the cost sharing in original Medicare also reflects this 20 percent coinsurance and it was included in Table 5 (Illustrative Contract Year 2022 In-Network Service Category Cost Sharing Limits) in the February 2020 proposed rule. Also consistent with Table 5 from the February 2020 proposed rule: the cost sharing limit for home health is 20 percent coinsurance for MA plans that choose a lower MOOP type and the cost sharing limit for each of the DME service categories is 20 percent coinsurance for MA plans that choose a mandatory MOOP type. As such, making a transition to that coinsurance limit is unnecessary (even for standards applied to the intermediate MOOP limit finalized in section II.A. of this FC, which are technically newly codified but are consistent with standards for the voluntary and mandatory MOOP limits from prior contract years). For example, in contract year 2022 the coinsurance limit for the "therapeutic radiological services" service category for MA plans is 20 percent, regardless of the MOOP type chosen. Following the methodology set through this FC, the "therapeutic radiological services" service category coinsurance limit that will be applicable for contract year 2023 and future years for MA plans that establish an intermediate MOOP limit will be 20 percent. MA organizations were able to, and may continue to, establish cost sharing equal to original Medicare for all benefits subject to paragraph (j)(1) in contract year 2021 and prior years by using coinsurance structures, which

some MA organizations may have chosen to do because of geographic variation in health care costs.

For purposes of calculating the actuarially equivalent copayment differential defined in § 422.100(f)(8)(i), the actuarially equivalent copayment values for service categories subject to § 422.100(j)(1) are based on 20 percent coinsurance, except for: skilled nursing care (as finalized in paragraph (j)(1)(i)(C)), home health services (for MA plans with an intermediate or mandatory MOOP, as finalized in paragraph (j)(1)(i)(D)), and each of the DME service categories (for MA plans with a lower or intermediate MOOP, as finalized in paragraph (j)(1)(i)(E)). We clarify this point because paragraph (f)(8)(i) requires use of the coinsurance limits that would apply in 2026, which is necessary for service categories subject to paragraph (f)(6)(iii), where the coinsurance percentages are changing over time. For purposes of paragraph (j)(1), the applicable coinsurance percentage is the same for contract years 2023 through 2026 and thereafter, unless the cost sharing requirements in original Medicare change. We are including a reference to paragraph (f)(8) in paragraph (j)(1) to apply the multi-year transition for copayment limits to the copayment limits calculated for these services.

CMS may calculate copayment limits for service categories subject to § 422.100(f)(6) and (j)(1) in contract year 2023 and subsequent years if we believe calculating such a copayment limit is feasible and appropriate to carry out program purposes, such as to protect beneficiaries against discriminatory cost sharing or to have further oversight of MA plans to ensure compliance with the regulatory standards. While certain factors complicated providing illustrative copayment amounts for all of the service categories listed in paragraph (j)(1) at the time of the February 2020 proposed rule, we are providing final contract year 2023 copayment limits in Table 28 for most of these service categories. The calculations to reach the contract year 2023 copayment limits for service categories subject to paragraph (j)(1) in Table 28 use contract year 2023 Medicare FFS data projections (based on 2017 – 2021 Medicare FFS data) and comply with the requirements in new paragraphs (f)(7) and (8). This includes projecting cost

sharing which may be incurred by beneficiaries in 2023 using generally accepted actuarial principles and practices (as finalized in paragraph (f)(7)(i)).

As described in $\S 422.100(f)(7)(ii)(C)$, when there may be multiple or a range of actuarially equivalent copayment values for a service category, CMS will select a particular approach to calculate an actuarially equivalent copayment value to avoid disruptive changes for beneficiaries and plan designs. For example, CMS may choose to use the median rather than the average Medicare FFS allowed amount to calculate an actuarially equivalent copayment value for a service category subject to § 422.100(j)(1) if that measure of central tendency results in the least amount of change to the copayment limit from the prior contract year. This approach is consistent with our prior approach to set copayment limits. We may also consider choosing the median or average Medicare FFS allowed amount based on which value is most consistent with trends and patterns in MA utilization and costs (if available). For example, in the February 2020 proposed rule, we explained that CMS proposed to add new cost sharing limits for an inpatient hospital acute 3-day length of stay scenario because it represented the median length of stay based on separate analyses of Medicare FFS and MA encounter data (for the same time period). A similar comparison may be completed if MA encounter data is also available related to a service category subject to paragraph (j)(1). While helpful for comparison purposes and to inform which measure of central tendency CMS should use, MA encounter cost data will not be used to calculate the copayment limits. This approach further protects beneficiaries and plan designs from potentially disruptive changes to cost sharing. New paragraph (f)(7) is discussed in greater detail in section II.B.5.a. of this FC.

Tables 25A and 25B show the calculations to reach the transitional contract year 2023 copayment limits for service categories subject to paragraphs § 422.100(j)(1) and (f)(8). As shown in row D in Tables 25A and 25B, for most of the service categories subject to paragraph (j)(1), we calculated an actuarially equivalent value to the original Medicare coinsurance requirement using contract year 2023 Medicare FFS data projections (based on 2017 – 2021

Medicare FFS data). The total projected Medicare FFS cost for each service category in Tables 25A and 25B is based solely on Medicare FFS data (MA encounter data for the same time period was unavailable at the time of writing this FC). In addition, the total projected Medicare FFS cost reflects the lesser value of the median and weighted average amount (in selecting among these actuarial approaches, we selected the lesser value) for each of the service categories in Tables 25A and 25B. This approach results in the least amount of change from the copayment limits set for contract year 2022 and is consistent with avoiding unnecessary fluctuations in cost sharing as finalized in paragraph (f)(7)(ii)(C). As a result, we calculate the actuarially equivalent values based on a 20 percent coinsurance limit regardless of the type of MOOP limit for most of the service categories subject to paragraph (j)(1) (as illustrated in Tables 25A and 25B). This excludes all of the DME service categories for the lower and intermediate MOOP types, for which actuarially equivalent copayment values are based on a 50 percent coinsurance limit as discussed in section II.B.5.a. of this FC. In addition, for the following two service categories subject to paragraph (i)(1) the original Medicare cost sharing limit is unique: \$0 for the first twenty days and one-eighth of the projected Part A deductible per day for days 21 - 100 of skilled nursing care (paragraph (j)(1)(i)(C)) and \$0 for home health services (paragraph (i)(1)(i)(D)). Specifically, for those benefits, CMS is finalizing regulation text with specific cost sharing limits to ensure that MA plans use cost sharing that does not exceed cost sharing in original Medicare:

- Skilled nursing care: Codifies specific cost sharing limits for days 1 20 in § 422.100(j)(1)(i)(C) based on the type of MOOP limit established and a specific methodology to calculate cost sharing limits for days 21 100, regardless of the MOOP amount established calculated, in paragraph (j)(1)(i)(C)(1).
- Home health: Applies the original Medicare cost sharing of \$0 for MA plans that establish a mandatory or intermediate MOOP type and uses an actuarially equivalent value to 20

percent coinsurance to calculate the cost sharing limit for MA plans that establish a lower MOOP limit, in paragraph (j)(1)(i)(D).

Barring these exceptions and as shown in Tables 25A and 25B, a value that is actuarially equivalent to 20 percent coinsurance for a particular service category subject to § 422.100(j)(1) was compared to the contract year 2022 copayment limit for the same service category. The difference between those two values equals the actuarially equivalent copayment differential (which is a unique figure for each service category and contract year). Then, we took 25 percent of the actuarially equivalent copayment differential and added it to the contract year 2022 copayment amount and applied the rounding rules in § 422.100(f)(6)(ii) to reach the transitional copayment for that service category based on the first year of the actuarially equivalent copayment transition. The values in row I in Tables 25A and 25B are the result of this application of the formula in paragraph (f)(8)(ii). As discussed in section II.B.5.b. of this FC, paragraph (f)(8) requires CMS to set the copayment limit for a given year at the value that is the lesser of amounts resulting from: (1) an actuarially equivalent value to the applicable cost sharing standard (in paragraphs (f)(6)(iii) and (j)(1)); and (2) an amount resulting from the actuarially equivalent copayment transition formula in paragraph (f)(8)(ii). To illustrate this comparison, row J in Tables 25A and 25B compares all of the transitional values from row I (resulting from paragraph (f)(8)(ii)) to the actuarially equivalent value to the applicable cost sharing standard in row E (20 percent coinsurance for most service categories subject to paragraph (i)(1)). As shown in row J of Tables 25A and 25B, all of the transitional values are less than (or equal to) the actuarially equivalent amount to cost sharing under original Medicare. As a result, the "lesser of" values in row J of Tables 25A and 25B are used in Table 28 as the final contract year 2023 copayment limits for those service categories and applicable MOOP types. By following the "lesser of" requirement in paragraph (f)(8) and choosing the measure of central tendency which produces the least amount of change from the prior contract year (as

allowed in paragraph (f)(7)) when calculating actuarially equivalent values, we aim to avoid potentially disruptive copayment changes for enrollees and plan designs.

TABLE 25A: CMS CALCULATIONS OF THE CONTRACT YEAR 2023 ACTUARIALLY EQUIVALENT COPAYMENT TRANSITION (§ 422.100(f)(8)) FOR SERVICE CATEGORIES IN PBP SECTIONS 6A, 8B, AND 11C SUBJECT TO COST SHARING NO GREATER THAN ORIGINAL MEDICARE (§ 422.100(j)(1)) USING CONTRACT YEAR 2023 MEDICARE FFS DATA PROJECTIONS (BASED ON MEDICARE FFS DATA FROM 2017 – 2021)

Row		Home	Therapeutic Radiological	DME-Diabetic Shoes or	DME-Diabetes Monitoring
Reference	Description	Health ¹	Services	Inserts ²	Supplies ²
A	Contract year 2022 copayment limit	\$35.00	\$60.00	\$10.00	\$10.00
В	Contract year 2023 total Medicare FFS projected cost ³	\$271.00 ⁴	\$414.005	\$47.51 ⁶	\$39.486
C	Coinsurance limit per § 422.100(j)(1)				20%
D	Unrounded actuarially equivalent copayment value to contract year 2023 coinsurance limit per § 422.100(j)(1) (row B multiplied by row C) (This figure is used to calculate the actuarially equivalent copayment differential as defined in § 422.100(f)(8)(i).) ⁷	\$54.20	\$82.80	\$9.50	\$7.90
E	Rounded actuarially equivalent copayment value to coinsurance limit per § 422.100(j)(1) (row D rounded per § 422.100(f)(6)(ii))	\$55.00	\$85.00	\$10.00	\$10.00
F	Actuarially Equivalent Copayment Differential per § 422.100(f)(8)(i) (difference between row A and row D)	\$19.20	\$22.80	(\$0.50)	(\$2.10)
G	25% of the Actuarially Equivalent Copayment Differential per § 422.100(f)(8)(ii)(A) (row F multiplied by 0.25)	\$4.80	\$5.70	(\$0.12)	(\$0.53)
Н	Unrounded copayment value result from actuarially equivalent copayment transition formula for contract year 2023 per § 422.100(f)(8)(ii)(A) (row A plus row G)	\$39.80	\$65.70	\$9.88	\$9.47
I	Rounded copayment value result from actuarially equivalent copayment transition formula for contract year 2023 per § 422.100(f)(8)(ii)(A) (row J rounded per § 422.100(f)(6)(ii))	\$40.00	\$65.00	\$10.00	\$10.00
J	Contract year 2023 "lesser of" copayment value per § 422.100(f)(8) (the lesser value comparing row E and row I)	\$40.00	\$65.00	\$10.00	\$10.00

¹The 20 percent coinsurance limit for home health (reflected in this table) only applies to MA plans that use the lower MOOP limit per § 422.100(j)(1)(i)(D). The home health copayment limit for the mandatory and intermediate MOOP limits is \$0 in alignment with original Medicare that has no cost sharing for home health.

TABLE 25B: CMS CALCULATIONS OF THE CONTRACT YEAR 2023 ACTUARIALLY EQUIVALENT COPAYMENT TRANSITION (§ 422.100(f)(8)) FOR SERVICE CATEGORIES IN PBP SECTIONS 12 AND 15 SUBJECT TO COST SHARING NO GREATER THAN ORIGINAL MEDICARE (§ 422.100(j)(1)) USING CONTRACT YEAR 2023 MEDICARE FFS DATA PROJECTIONS (BASED ON MEDICARE FFS DATA FROM 2017 – 2021)

²The 20 percent coinsurance limit for the DME service categories (reflected in this table) only applies to the mandatory MOOP limit. As discussed in section II.B.5.a. of this FC and as shown in Table 28, the 50 percent coinsurance limit and associated actuarially equivalent copayment limit for DME service categories applies only to the lower and intermediate MOOP limits.

³The OACT employed generally accepted actuarial principles and practices in calculating these projected amounts (as finalized in § 422.100(f)(7).

⁴This amount for the "home health" service category represents the projected total Medicare FFS weighted average per visit cost for contract year 2023, including services in the Medicare FFS home health bundle (such as, nurse, aid, therapist, certain medical supplies and medications) but no other services (such as other medications, supplies, and DME). ⁵This amount for the "therapeutic radiological services" service category represents the projected total Medicare FFS median per session cost for contract year 2023.

⁶These amounts represent the projected total Medicare FFS weighted average cost for contract year 2023, weighted by utilization of the various types for the DME "diabetic shoes or inserts" and "diabetes monitoring supplies" service categories.

Section 422.100(f)(8)(i) requires use of Medicare FFS data projections based on the coinsurance limits that would apply in 2026, which is necessary for service categories subject to paragraph (f)(6)(iii), where the coinsurance percentages are changing over time. For purposes of paragraph (j)(1), the applicable coinsurance percentage is the same for contract years 2023 through 2026 and thereafter, unless the cost sharing requirements in original Medicare change.

			Part B Drugs	
Row		Dialysis	Chemotherapy/	Part B Drugs-
Reference	Description	Services	Radiation Drugs	Other
A	Contract year 2022 copayment limit	\$30.00	\$75.00	\$50.00
В	Contract year 2023 total Medicare FFS projected cost ¹	\$321.002	$$1,397.00^{3}$	\$1,603.004
C	Coinsurance limit per § 422.100(j)(1)			20%
D	Unrounded actuarially equivalent copayment value to contract year 2023 coinsurance limit per	\$64.20	\$279.40	\$320.60
	§ 422.100(j)(1) (row B multiplied by row C) (This figure is used to calculate the actuarially equivalent			
	copayment differential as defined in § 422.100(f)(8)(i).) ⁵			
E	Rounded actuarially equivalent copayment value to coinsurance limit per § 422.100(j)(1) (row D rounded per	\$65.00	\$280.00	\$320.00
	§ 422.100(f)(6)(ii))			
F	Actuarially Equivalent Copayment Differential per § 422.100(f)(8)(i) (difference between row A and row D)	\$34.20	\$204.40	\$270.60
G	25% of the Actuarially Equivalent Copayment Differential per § 422.100(f)(8)(ii)(A) (row F multiplied by	\$8.55	\$51.10	\$67.65
	0.25)			
Н	Unrounded copayment value result from actuarially equivalent copayment transition formula for contract	\$38.55	\$126.10	\$117.65
	year 2023 per § 422.100(f)(8)(ii)(A) (row A plus row G)			
I	Rounded copayment value result from actuarially equivalent copayment transition formula for contract year	\$40.00	\$125.00	\$120.00
	2023 per § 422.100(f)(8)(ii)(A) (row J rounded per § 422.100(f)(6)(ii))			
J	Contract year 2023 "lesser of" copayment value per § 422.100(f)(8) (the lesser value comparing row E and	\$40.00	\$125.00	\$120.00
	row I)			

The OACT employed generally accepted actuarial principles and practices in calculating these projected amounts (as finalized in § 422.100(f)(7).

²This amount for the "dialysis services" service category represents the total weighted average cost per session for contract year 2023 (including facility fees and approximated physician fees). This amount considers all types of dialysis and settings (such as, hospital outpatient departments and provider offices).

³This amount for the "Part B drugs-chemotherapy/radiation drugs" service category represents the projected total Medicare FFS median per session cost for contract year 2023.

This amount reflects costs from betos/HCPC codes that have a chemotherapy grouper and takes into consideration drug, administration, and place of service costs.

⁴This amount for the "Part B drugs-other" service category represents the projected total Medicare FFS median allowed amount for contract year 2023.

⁵Section 422.100(f)(8)(i) requires use of Medicare FFS data projections based on the coinsurance limits that would apply in 2026, which is necessary for service categories subject to paragraph (f)(6)(iii), where the coinsurance percentages are changing over time. For purposes of paragraph (j)(1), the applicable coinsurance percentage is the same for contract years 2023 through 2026 and thereafter, unless the cost sharing requirements in original Medicare change.

Tables 25A and 28 contain final contract year 2023 copayment limits for only two of the DME service categories (specifically, the DME "diabetic shoes or inserts" and "diabetes monitoring supplies" service categories). CMS is not calculating a copayment limit for the other DME service categories listed in § 422.100(j)(1)(i) for contract year 2023. Therefore, MA organizations that use copayments for those other DME service categories in contract year 2023 must establish a copayment that does not exceed an actuarially equivalent value to the coinsurance required under original Medicare. CMS may calculate copayment limits for the other DME service categories in a future year if sufficient Medicare FFS data projections become available and it is appropriate for program purposes, as provided in § 422.100(f)(7)(ii). We reiterate that, beginning for contract year 2024, paragraph (f)(7)(iii) applies in that CMS will issue guidance and may solicit public comment on the actuarial approaches used to reach an actuarially equivalent copayment value for each copayment limit CMS calculates. In general, CMS will follow § 422.100(f)(7), (f)(8) and (j)(1) to calculate copayment limits for contract year 2023 and subsequent years for the benefits specified in paragraph (i)(1). This is consistent with the general approach we took in the February 2020 proposed rule in that the same rules would apply for the professional services if CMS issues copayment limits, regardless of whether we had illustrative cost sharing limits to share at the time of the February 2020 proposed rule.

We do not expect that calculating copayment limits at values that are less than a value that is actuarially equivalent to original Medicare (based on the most recent Medicare FFS data projections) during the applicable transition year(s) will directly result in MA organizations incorporating higher MOOP amounts, increasing premiums, or reducing supplemental benefits in their plan designs. This is because MA organizations can continue to use coinsurance that does not exceed cost sharing under original Medicare. Further, applying this methodology we are finalizing – to use actuarially equivalent values subject to a cap that acts to transition changes from the copayment limits set for contract year 2022 copayment limits to actuarially equivalent values – is projected to increase copayment limits from the contract year 2022 levels for service

categories subject to § 422.100(j)(1). In addition, if the actuarially equivalent copayment amount did not reflect a substantive change in comparison to the cost sharing limit set in contract year 2022, the contract year 2023 copayment limit may reflect the full amount. As shown in Tables 25A and 28, this is the case for the DME "diabetic shoes and inserts" and "diabetes monitoring supplies" service categories for the mandatory MOOP limit. The \$10 copayment limit from contract year 2022 for both of these service categories remains unchanged for contract year 2023 because \$10 reflects an actuarially equivalent value to 20 percent coinsurance after application of the rounding rules in § 422.100(f)(6)(ii), using contract year 2023 Medicare FFS data projections (based on 2017 – 2021 Medicare FFS data).

MA organizations may have benefit designs that include different copayment levels within the same service category (referred to as minimum and maximum copayment in the plan benefit package software). This capability helps address service categories that may include a wide range of items or services with lower and higher costs, such as Part B drugs. For example, a plan can have a lower copayment amount for lower cost services and a higher copayment amount for other higher cost services within the same service category, as long as the cost sharing satisfies CMS standards.

Table 26 provides an illustrative example of how the copayment limits may change in future years for a particular service category subject to § 422.100(j)(1) as more of the actuarially equivalent copayment differential is incorporated and the "lesser of" value is used to set copayment limits during the transitional period. Specifically, Table 26 provides the final contract year 2023 cost sharing limits and illustrative copayment limits across the multiyear transition schedule to actuarially equivalent values for the "Part B Drugs – chemotherapy/radiation drugs" service category using contract year 2023 Medicare FFS data projections (based on 2017 – 2021 Medicare FFS data). We reiterate that the copayment limits for contract years 2024 through 2026 in Table 26 remain illustrative in nature and may change based on updated and more recent Medicare FFS data projections in future years. Projections for contract years after 2023 were not

available at the time of writing this FC and the copayment limits for those years in Table 26 illustrate the transition over the 4 years.

TABLE 26: FINAL CONTRACT YEAR 2023 AND ILLUSTRATIVE CONTRACT YEAR 2024 – 2026 COST SHARING LIMITS FOR THE "PART B DRUGS – CHEMOTHERAPY/RADIATION" SERVICE CATEGORY SUBJECT TO § 422.100(j)(1) USING ON CONTRACT YEAR 2023 MEDICARE FFS DATA PROJECTIONS (BASED ON 2017 - 2021 MEDICARE FFS DATA)

Contract Year	Cost Sharing Limit
20221	20% / \$75
2023^2	20% / \$125
2024 ³	20% / \$175
2025^{3}	20% / \$230
2026^{3}	20% / \$2804

¹The cost sharing limits for contract year 2022 are provided for comparison purposes.

Table 26 illustrates how implementing a multiyear transition to actuarially equivalent copayment values with the "lesser of" requirement avoids the sudden significant and potentially disruptive increases that would occur without such a transition. Specifically, for the "Part B Drugs – Chemotherapy/Radiation" service category, which had a \$75 copayment limit in contract year 2022, it transitions the \$205 difference from the 2022 amount and the actuarially equivalent value of \$280 by approximately \$50 increments annually until the actuarially equivalent value is reached in contract year 2026. We acknowledge in order to reach an actuarially equivalent copayment limit during what we consider a reasonable transition timeframe of 4 years, the year over year change in the copayment limit for some service categories subject to paragraph (j)(1) is more than what CMS likely would have adopted in prior years. Applying this multiyear transition to benefits that must not exceed cost sharing under original Medicare will strike a balance in making the changes necessary to reach actuarially equivalent copayments while protecting beneficiaries. In addition, we believe that it is important to begin transitioning copayment limits to be actuarially equivalent to the cost sharing in original Medicare to encourage MA plans to consider copayments instead of coinsurance. As noted in

²The contract year 2023 cost sharing limits are final and calculated using § 422.100(f)(7), (f)(8), and (j)(1).

³The copayment limits for these years are illustrative and final amounts will be announced using the subregulatory process at § 422.100(f)(7)(iii) using updated Medicare FFS data projections.

⁴This is the first year that the copayment limit is projected to reach an actuarially equivalent value to the 20 percent coinsurance limit

the February 2020 proposed rule, although MA plans have the flexibility to establish cost sharing amounts as copayments or coinsurance, enrollees generally find copayment amounts more predictable and less confusing than coinsurance⁵⁶. By updating copayment limits to reflect the expected costs of providing the benefit based on the most recent Medicare FFS data projections, we expect more MA organizations may consider copayment structures when designing their cost sharing. In addition, we expect that MA organizations will be able to plan aspects of their benefit designs several years in advance based on the projected copayment limits CMS is sharing through this FC and through the specific transition codified in § 422.100(f)(8). We do not anticipate significant increases in enrollee cost sharing as a result of these changes in cost sharing standards. About 98 percent of contract year 2021 MA plans (including D-SNPs and institutional and chronic condition SNPs) have supplemental benefits that reduce Part A and B cost sharing and 93 percent of these plans use a portion of their rebates to pay for some or all of the reduced cost sharing of Part A and B benefits (the other 7 percent and any amount remaining after applying a portion of rebates have the reduction of cost sharing paid for through the member's premium). Excluding SNPs, 100 percent of contract year 2021 MA plans have supplemental benefits that reduce cost sharing and 94 percent use a portion of their rebates to pay for some or all of that benefit (after applying a portion of the rebates, any amount remaining is paid through the member's premium).

As also discussed in section II.B.5.b. of this FC, CMS is finalizing new § 422.100(f)(8) to transition current (contract year 2022) copayment limits to actuarially equivalent values by contract year 2026. The completion of the transition to actuarially equivalent copayment values as provided in new paragraph (f)(8) means that CMS will annually update the copayment limits (including those subject to § 422.100(j)(1)) to new actuarially equivalent values based on the

⁵⁶ Loewenstein G, Friedman JY, McGill B, Ahmad S, Linck S, Sinkula S, Beshears J, J.Choi J, Kolstad J, Laibson D, Madrian BC, List JA, Volpp KG. "Consumers' misunderstanding of health insurance". Journal of Health Economics 2013;32(5):850-862. Retrieved from: https://scholar.harvard.edu/laibson/publications/consumers-misunderstanding-health-insurance

most recent Medicare FFS data projections available (subject to the rounding rules in paragraph (f)(6)(ii)) beginning for contract year 2026 and subsequent years. We believe annually updating copayment limits ensures that all cost sharing limits are consistent with cost sharing in original Medicare, will provide a measure of predictability and stability for MA organizations, and ensures copayment limits do not become outdated in future years.

Comment: A few commenters opposed implementing the statutory requirement (section 1852 (1)(B)(iv) of the Act, currently implemented § 422.100(j)(2) and proposed to be redesignated in this rulemaking) that requires MA plans to establish cost sharing for renal dialysis services that does not exceed the cost sharing under original Medicare (that is, 20 percent coinsurance or an approximate actuarially equivalent copayment). These commenters suggested that this level of cost sharing is discriminatory and would substantially discourage enrollment by beneficiaries who require dialysis services. A commenter noted that the MOOP limit is insufficient to prevent enrollees with diagnoses of ESRD from experiencing cost-prohibitive dialysis cost sharing based on the MA organization's ability to charge up to 20 percent coinsurance; the commenter also stated these situations are counter-productive to enrollees' health should they be unable to afford such ongoing costs prior to the triggering the MOOP limit. The commenters requested that CMS: (1) prohibit any cost sharing or, at the least, lower the cost sharing limit for dialysis services for all MA plans regardless of the MOOP limit established; and (2) issue clear statements to MA plans before the contract year 2021 bid deadline (June 1, 2020) that benefit designs that establish a 20 percent coinsurance for dialysis services are discriminatory and will not be allowed.

A commenter noted a mandate of zero cost sharing for dialysis across all types of MOOP limits would ensure that all plans are on an even footing in their plan offerings, and beneficiaries would have access to the optimal benefit structure most likely to duplicate the positive results achieved by chronic condition SNPs (C-SNPs) and ESRD Seamless Care Organization (ESCOs). The commenter stated that while this approach is beneficiary-friendly, it does have a drawback

in that MA plans which enroll a disproportionate share of ESRD patients could suffer relative to competitors. However, the commenter noted a zero-cost sharing mandate also would permit plans to encourage patient adherence to dialysis without fear of attracting too many ESRD patients. The commenter explained such a mandate would be consistent with the agency's interest in promoting value-based insurance design (VBID) principles.

Another commenter cited several provisions (the anti-discrimination provisions in section 1852(b)(1) of the Act and section 3202 of the Affordable Care Act (ACA), which added the statutory requirement that MA plans have cost sharing for renal dialysis (and other services) that does not exceed cost sharing in original Medicare, and § 422.100(f)(2)), and CMS's review of bids as the basis for requesting that CMS ensure MA plans' cost sharing designs do not discriminate against individuals with ESRD. A commenter stated that charging maximum costsharing that is permissible under the law for a particular service used by a particular population could be viewed as discriminatory on its face. This commenter explained that the intent of cost sharing is to prevent the over-utilization of health care services, but that dialysis is a regular, medically necessary service for a population with a particular diagnosis and not a service that is over-utilized by those diagnosed with ESRD. Therefore, the commenter believed that dialysis was not a service that would benefit from cost sharing limits that were designed to control utilization. The commenter also stated that an MA plan that changes from zero cost sharing for dialysis services to a 20 percent coinsurance from one contract year to next, may discourage individuals with ESRD from staving enrolled in the plan or may unintentionally discourage people requiring dialysis from enrolling in the plan. The commenter further noted that once the right for any Medicare beneficiary with ESRD to enroll in any MA plan is effective in 2021, an MA plan's use of 20 percent cost sharing would encourage such enrollees to look for plans that do not impose such costs. The commenter noted CMS has already approved benefit designs for the 2020 contract year that have 20 percent coinsurance for dialysis services. In effect, the commenter stated if benefit designs with 20 percent coinsurance for dialysis services becomes

the norm, MA plans might attempt to dissuade enrollment by individuals with ESRD across the board.

Response: Section 1852(a)(1)(B)(iv) of the Act and § 422.100(j) already require MA plans to have cost sharing that does not exceed that in original Medicare for renal dialysis services; our proposal was to re-designate that provision and it is being finalized as paragraph (i)(1)(i)(B). We appreciate the feedback on this provision and recommendations to adopt a stricter standard for cost sharing for renal dialysis. This regulation implements the statutory requirement in section 1852(a)(1)(B)(iv) of the Act, which has been in place since 2011, that MA plans use cost sharing that does not exceed the cost sharing in original Medicare for renal dialysis services (as defined in section 1881(b)(14)(B) of the Act). Under this statute, CMS has allowed MA organizations to establish a coinsurance up to 20 percent for dialysis services since 2011.⁵⁷ We nonetheless do not believe the anti-discrimination provisions in section 1852(b)(1) of the Act and § 422.100(f)(2) would be violated merely by permitting an MA plan to use the same coinsurance amounts that are used in the original Medicare program. This is consistent with longstanding MA program requirements that plan bids be at least actuarially equivalent to original Medicare on an overall basis. In addition, as the 20 percent coinsurance limit for dialysis services is equally applicable to the original Medicare and MA programs, the additional requirements of a MOOP limit and the ability to receive supplemental benefits through an MA plan may address the commenter's concern about beneficiaries with diagnoses of ESRD being discouraged from enrolling in MA plans compared to the Medicare FFS program. In relation to the commenter's request to mandate a zero cost sharing limit for dialysis across all types of MOOP limits to ensure that all plans are on an even footing in their plan offerings, we note that the MA program was established to provide options in addition to the original Medicare program

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⁵⁷ Call Letters communicating CMS policy for contract years prior to 2021 may be accessed here: https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents.

for beneficiaries to obtain Medicare benefits and we believe this FC adopts policies to ensure the continued offering of MA plans that are viable options for Medicare beneficiaries as a whole.

The percentage of MA and MA-PD plans (excluding employer, D-SNP, and Medicare MSA plans) with zero cost sharing for dialysis services has remained relatively consistent between contract year 2012 (approximately 2.6 percent) and contract year 2021 (approximately 2.9 percent) based on March 2021 data. The vast majority of MA plans have designed their dialysis benefit with cost sharing greater than zero and use coinsurance rather than a copayment. The percentage of these MA plans with non-zero cost sharing that established the same coinsurance as original Medicare for dialysis services was approximately 94.7 percent in contract year 2012 and is approximately 99.9 percent for contract year 2021 (as a percentage of enrollment, 91.4 percent in contract year 2012 and 99.9 percent in contract year 2021). There are MA plans where coinsurance for dialysis services is equal to original Medicare and program enrollment of beneficiaries with diagnoses of ESRD has not decreased and, therefore, does not suggest that this aspect of MA plan designs is discouraging enrollment of enrollees with diagnoses of ESRD.⁵⁸ While that enrollment experience was during a time when there were limits on the ability of beneficiaries with ESRD to enroll in MA plans, we believe it is persuasive that the ability for MA plans to have cost sharing for dialysis services that is equal to the cost sharing used in original Medicare does not in and of itself discourage enrollment of beneficiaries with diagnoses of ESRD.

The contract year 2022 copayment limit of \$30 for dialysis services has been in place for a number of years and does not reflect a current actuarially equivalent value equal to 20 percent coinsurance based on contract year 2023 Medicare FFS data projections (based on 2017 – 2021 Medicare FFS data). Under the current regulation at § 422.100(f)(6), the contract year 2022 copayment limit for dialysis services was originally set to strike a balance between limiting

⁵⁸ See enrollment projections for ESRD enrollment, See page 14 from the 2020 Rate Notice and Final Call Letter, retrieved from https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2020.pdf.

beneficiary out-of-pocket costs the and potential impact to plan design and costs, with the goal of ensuring beneficiary access to affordable and sustainable benefit packages. Since most MA plans use 20 percent coinsurance for the cost sharing for dialysis services, calculating a copayment limit that is lower than the coinsurance level does not actually result in lower out of pocket cost sharing payments by enrollees. Setting copayment limits using actuarially equivalent values to cost sharing under original Medicare (20 percent coinsurance for most services categories subject to § 422.100(j)(1)) would, in effect, recalibrate copayment limits compared to current levels. We believe that this recalibration and better alignment of the copayment and coinsurance limits for dialysis services, like for the other services listed in § 422.100(j)(1), is important to incentivize MA organizations in how they structure cost sharing for enrollees and to have a more transparent methodology and process for MA cost sharing limits.

While an illustrative actuarially equivalent copayment limit for dialysis services was not available to share at the time of the February 2020 proposed rule, using contract year 2023 Medicare FFS data projections (based on 2017 – 2021 Medicare FFS data), calculating a copayment limit at an actuarially equivalent value equal to 20 percent coinsurance (after applying the rounding rules in § 422.100(f)(6)(ii)) would equal \$65, a substantive increase from the \$30 copayment limit used for contract year 2022. Less than 1 percent of 2021 plans that require cost sharing for dialysis (based on March 2021 data, excluding employer, D-SNP, and MSA plans) charge a copayment for these services in their benefit design. As previously discussed, we expect that transitioning copayment limits to be actuarially equivalent to the cost sharing in original Medicare will encourage MA plans to consider the use of copayments instead of coinsurance. However, given the potential disruption that could result from substantive increases in one year for those plans with copayments and to be responsive to commenters, CMS is adopting a multiyear transition to actuarially equivalent copayment limits for service categories subject to § 422.100(j)(1) (including dialysis services). This transition is finalized in new paragraph (f)(8) and explained more completely in section II.B.5.b. of this FC and in a prior response to comment in this section. In brief, applying this transition (and the "lesser of" requirement) moderated the increase to the copayment limit for dialysis services from \$30 in contract year 2022 to \$40 for contract year 2023 (as calculated in Table 25B and finalized in Table 28).

CMS contracts with MA organizations for one year at a time, and MA organizations may change their benefit designs and cost sharing structures annually within statutory and regulatory requirements. We remind commenters that existing statutory (Section 1852(a)(1)(B)(iv) of the Act) and regulatory requirements (§ 422.100(j)) require that renal dialysis services not exceed cost sharing under original Medicare (that is, 20 percent coinsurance). CMS will continue to monitor MA plan benefit designs to observe whether there is information indicating potential discrimination or efforts by MA plans to discourage enrollment by beneficiaries with diagnoses of ESRD. We are finalizing our proposal to keep this existing requirement and updating the redesignation to § 422.100(j)(1)(i)(B) from proposed paragraph (j)(1)(ii).

Comment: A few commenters generally supported the proposal (in section VI.B.3.c. of the February 2020 proposed rule) to codify CMS's existing policy to establish nominal cost sharing limits for the first 20 days in a skilled nursing facility (SNF) based on the type of MOOP limit. A commenter believed that the current level of differentiation between the cost sharing limits by the MOOP limit is reasonable and did not support increasing the differentiation any further. This commenter stated the utilization of this service is very low and increasing the cost sharing limit differentiation by the type of MOOP limit further would not provide a strong actuarial incentive for an MA organization to offer a lower (previously "voluntary") MOOP limit.

Response: We thank the commenters for their support. We proposed differentiating cost sharing limits across highly utilized services (for example, inpatient and primary care) and various other cost sharing services categories to produce a cumulative incentive for MA plans to use lower MOOP limits. We believe that MA organizations will have more incentive to establish

an MA plan with lower total MOOP costs for enrollees as a result of this FC which provides the greatest flexibility in designing cost sharing to lower MOOP limits and are finalizing that policy approach. In addition, we are finalizing § 422.100(j)(1)(i)(C) (which is an updated designation from paragraph (j)(1)(iii) in the February 2020 proposed rule) with additional requirements to address the per day cost sharing amounts for skilled nursing care that may be charged by MA plans that adopt the lower or intermediate MOOP type. Specifically, permissible cost sharing for the first 20 days must be no greater than \$20 per day for a plan with a lower MOOP amount and \$10 per day for plan with an intermediate MOOP amount; these are the nominal cost sharing figures from Table 5 (Illustrative Contract Year 2022 In-Network Service Category Cost Sharing Limits) in the February 2020 proposed rule for MA plans that use an intermediate or lower MOOP amount. Authority for these cost sharing amounts is limited to the first 20 days of a SNF stay. We believe detailing specific per day cost sharing is appropriate to ensure clarity in the regulation text regarding our proposal from section VI.B.3. of the February 2020 proposed rule.

We also take this opportunity to provide guidance as to how we intend to implement the SNF cost sharing limits in the current PBP data entry options. Consistent with current practice, MA organizations may indicate in the PBP that the plan establishes a coinsurance for the SNF service category instead of using the specific per day copayment amounts that are permitted. The process of developing supporting documentation that shows how the coinsurance meets the cost sharing standard under § 422.100(j)(1) is consistent with prior years and is referenced in our general discussion related to supporting documentation in section II.B.5.a. of this FC. In addition, MA organizations may submit their plan bids based on the CMS SNF copayment limits (in the regulation for the first 20 days and published prior to MA bid submission for days 21 through 100) or choose to indicate in the PBP SNF service category that the plan will use the actual Medicare FFS cost sharing amount for both SNF benefit periods, that is the first 20 days and days 21 through 100. CMS typically publishes the original Medicare cost sharing parameters (for example, Part A and B deductibles) a few months prior to the upcoming year, but

this generally happens well after the MA bid deadline. As explained in the preamble of the February 2020 proposed rule, we calculate the cost sharing limit for days 21-100 in a SNF by taking one-eighth of the projected Part A deductible for the contract year. To ensure clarity in the regulation on these points, we are finalizing a change to § 422.100(j)(1)(i)(C)(1) (that is an updated designation from § 422.100(j)(1)(iii)(A) in the February 2020 proposed rule), that the SNF cost sharing limit for days 21 to 100 is based on one-eighth (not the total amount) of the projected (or actual) Part A deductible. We are finalizing the remainder of what was proposed at § 422.100(j)(1)(iii)(B) as paragraph (j)(1)(i)(C)(2) and clarifying that the total cost sharing for the overall SNF benefit must not be greater than the PMPM actuarially equivalent cost sharing in original Medicare. CMS will utilize these regulatory standards for calculating cost sharing limits for SNF and evaluating MA plans during bid review.

Comment: A few commenters opposed allowing up to 20 percent coinsurance or the approximate actuarially equivalent copayment for home health services for MA plans with lower MOOP limits and allowing MA plans that establish a lower or intermediate MOOP limit the flexibility to set cost sharing limits for specific items of DME that exceed the cost sharing in original Medicare. These commenters requested CMS prohibit cost sharing for home health services consistently across all types of MOOP limits and not finalize the proposal to allow cost sharing flexibility for DME or, at the very least, require uniformity across MA plans with respect to cost sharing for DME. In lieu of prohibiting these cost sharing flexibilities for DME, the commenters requested that CMS provide guidance about what types of DME items can be subject to higher cost sharing rates under the proposal. They noted that cost sharing applied to certain DME that is typically used by beneficiaries with certain conditions can constitute discriminatory cost sharing on its face, particularly without guidance from CMS about what types of DME items can be subject to higher cost sharing rates under the proposal. In addition, the commenters stated that Medicare FFS does not charge cost sharing for home health and the application of the lower MOOP limit in the MA program should not be used to justify an MA

plan charging cost sharing for services that that are insulated from any costs in traditional Medicare.

Response: We appreciate the feedback on our proposals related to adding home health and DME to the list of services for which cost sharing charged by an MA plan may not exceed cost sharing required under original Medicare. The ability to use cost sharing for specific service categories of DME that exceeds the level of cost sharing used in the original Medicare program provides an acceptable level of incentive for MA organizations to offer plans with lower or intermediate MOOP limits, particularly when combined with the other flexibilities finalized in this FC, by balancing the overall protection for enrollees related to total out-of-pocket spending with the protection for cost sharing for specific benefits. As proposed and finalized, this flexibility is limited to use of the lower or intermediate MOOP limit and subject to both a requirement that the overall DME benefit be actuarially equivalent on a per member per month basis to cost sharing in original Medicare and the requirement that cost sharing for specific DME categories not exceed 50 percent of the estimated total MA plan financial liability for that contract year. Further, the intermediate and lower MOOP types provide additional protection for enrollees. These policies regarding DME cost sharing are consistent with longstanding CMS policy and how benefits have been submitted through the PBP. Taken together, we believe that these proposals related to cost sharing for DME will provide protection to MA enrollees from high out-of-pocket costs related to DME. Based on this, we do not believe additional regulatory standards are necessary at this time. We will continue to evaluate experience with this longstanding CMS policy during bid review and may revisit these requirements, if necessary, to ensure that our overall goals for the cost sharing policies are met, including that beneficiaries are not subject to discriminatory cost sharing structures or benefit designs that discourage enrollment based on significant health needs.

In approaching how to set cost sharing limits for DME, CMS is mindful that the category includes items and services that vary significantly in cost and that MA plans are not uniform in

whether and to what extent the MA organization uses specific contracting arrangements permitted by § 422.100(1). We did not intend to require MA plans to establish cost sharing at the individual item or service level for DME and it would not follow current industry practice, nor how benefits are submitted through the PBP, to do so. As indicated in Table 5 (Illustrative Contract Year 2022 In-Network Service Category Cost Sharing Limits) in the February 2020 proposed rule, the proposed service categories with higher cost sharing flexibility for MA plans that establish lower or intermediate MOOP limits for DME are: equipment, prosthetics, medical supplies, diabetes monitoring supplies, and diabetic shoes or inserts. However, this flexibility is limited by how, for all MA plans and regardless of MOOP type, the total cost sharing for all DME service categories combined must not exceed original Medicare on a per member per month actuarially equivalent basis. Under this FC, MA plans that establish a lower or intermediate MOOP limit may have cost sharing equal to or less than 50 percent coinsurance (or an actuarially equivalent copayment) for specific service categories of DME while MA plans that use a mandatory MOOP limit must have cost sharing that does not exceed cost sharing in original Medicare for DME in those categories. We finalize this flexibility in proposed § 422.100(j)(1)(v) as paragraph (j)(1)(i)(E) with a modification to reference the specific service categories of DME (equipment, prosthetics, medical supplies, diabetes monitoring supplies, diabetic shoes or inserts). This flexibility is consistent with previous CMS policy and subject to the requirement in § 422.100(f)(6)(i) that an MA plan must pay at least 50 percent of the estimated total MA plan financial liability for that contract year where another, more specific rule on cost sharing limits does not apply. We provide a more complete discussion of this requirement in section II.B.5.a. of this FC. In brief, this rule that cost sharing cannot exceed 50 percent of the MA plan's estimated total financial liability for that contract year applies to DME at the service category level and in addition to the specific cost sharing rules that apply to items and services under paragraph (j) or rules other than paragraph (f)(6).

To provide additional transparency and better guidance on the level of cost sharing allowed for DME service categories for MA plans that establish a lower or intermediate MOOP amount, as discussed in section II.B.5.a. of this FC, the "N/A" descriptions that were used in Table 5 (Illustrative Contract Year 2022 In-Network Service Category Cost Sharing Limits) from the February 2020 proposed rule are updated to 50 percent in Table 28 (which generally updates the information from Table 5 in the February 2020 proposed rule). We believe this change better reflects how the requirement at § 422.100(f)(6)(i), that the MA plan pay at least 50 percent of estimated total MA plan financial liability for that contract year, applies to the cost sharing for service categories of DME for MA plans with the lower or intermediate MOOP amounts while the requirement of 20 percent coinsurance applies only to MA plans with a mandatory MOOP amount. As indicated in the footnotes of Table 28, all MA plans must have total cost sharing for the overall DME benefit that is not greater than the per member per month actuarially equivalent cost sharing for the DME benefit in original Medicare. The clarifications discussed previously are incorporated into the final language in § 422.100(j)(1)(i)(E).

If CMS does not calculate an actuarially equivalent copayment limit for any of the DME service categories, MA organizations may still establish an actuarially equivalent copayment to the applicable coinsurance limit instead of using coinsurance. This is consistent with footnote 5 from Table 5 (Illustrative Contract Year 2021 In-Network Service Category Cost Sharing Limits) in the February 2020 proposed rule, which noted that MA plans may establish a copayment that is actuarially equivalent to, or less than, the applicable coinsurance limit for service categories for which CMS does not calculate a copayment limit (85 FR 9087). The information in this footnote is updated to reflect our final policy in footnote 7 from Table 28. Specifically, for DME service categories without a copayment limit calculated by CMS, MA organizations may establish a copayment based on the average Medicare FFS allowable amount for the plan service area or their estimated total MA plan financial liability for the benefit (subject to the rounding rules in § 422.100(f)(6)(ii)) as finalized in paragraph (f)(6)(i) (for the lower and intermediate

MOOP limits) and § 422.100(j)(1)(i) (for the mandatory MOOP limit). For example, CMS did not set a final contract year 2023 copayment limit for the DME "equipment" service category and MA plans may calculate an actuarially equivalent copayment for that service category using the rules in paragraph (j)(1)(ii) for that contract year. Further information on how MA organizations may calculate actuarially equivalent copayments and develop supporting documentation in the absence of a copayment limit calculated by CMS is available in section II.B.5.a. of this FC. CMS will continue to gather and review the data described in finalized § 422.100(f)(7)(ii) for use in calculating copayment limits related to the remaining DME service categories for future years and we may calculate copayment limits for these categories in the future.

CMS also proposed to codify our longstanding policy of limiting cost sharing for home health services for MA plans that establish a mandatory or intermediate MOOP amount to that charged under original Medicare and 20 percent coinsurance for plans with a lower MOOP amount. As discussed in the February 2020 proposed rule, maintaining the maximum cost sharing flexibility for lower MOOP limits acts as an important incentive for plans to offer a lower MOOP amount, which is another important financial protection for beneficiaries. We generally rely on our authority at 1852(a)(1)(B)(iv)(IV) of the Act to apply original Medicare cost sharing limits to other Part A or B benefits that the Secretary determines appropriate; for benefits where cost sharing in original Medicare is zero, we also rely on our authority in section 1856(b)(1) of the Act to calculate MA standards by regulation, and in section 1857(e)(1) of the Act to impose additional terms and conditions found necessary and appropriate to require that cost sharing for these services under MA plans conform to that under original Medicare, meaning that no cost sharing could be imposed for these services. Despite the limitation in section 1852(a)(1)(B)(v) of the Act on our authority to identify additional benefits for which MA cost sharing must not exceed the cost sharing in original Medicare, we believe that it is necessary and appropriate to limit cost sharing for these services to avoid discouraging enrollment by

beneficiaries who need those services and to incentivize MA plans to use the lower MOOP limits. This FC generally limits cost sharing to zero for those services where original Medicare does not impose costs only when an MA plan establishes a mandatory or intermediate MOOP amount. Therefore, an MA plan is not prohibited from using cost sharing for these services and may elect to use cost sharing for them by establishing a lower MOOP amount. In addition, codifying specific benefit standards that we believe are appropriate for MA plan designs provides transparency as to how CMS would use its authority under section 1854(a)(5)(C)(i) and (a)(6)(B) of the Act to evaluate and negotiate bids for MA contracts. Overall, this approach to regulating cost sharing is consistent with the statute as it protects beneficiaries while also preserving a measure of flexibility for MA plans. Finally, we believe that maintaining this longstanding standard does not limit market competition and we expect beneficiary choice will continue to act as an incentive for MA organizations to offer favorable benefit designs.

With regard to comments about MA plans being able to include cost sharing for home health when original Medicare does not permit cost sharing, we note that commenters on the Final Rule titled "Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2012 and Other Changes" published April 15, 2011 (referred to as the April 2011 Final Rule), including MedPAC, opposed CMS's prior proposal to limit cost sharing for home health services, under MA and cost plans at original Medicare levels. For example, in the April 2011 Final Rule, MedPAC commented that home health cost sharing should be one of the tools that MA plans can use at their discretion as a means of ensuring appropriate utilization. In addition, MedPAC's March 2020 "Report to Congress: Medicare Payment Policy," Chapter 9 Home Health Care Services (page 258), states the following: "Medicare does not provide any incentives for beneficiaries or providers to consider alternatives to home health care, such as outpatient services. Beneficiaries who meet program coverage requirements can receive an unlimited number of home health episodes and face no cost sharing." We agree that finalizing the flexibility for MA plans in connection with

cost sharing for these benefits where original Medicare does not have cost sharing is appropriate for these reasons as well as others discussed throughout this FC for our cost sharing policies. MA plans that establish a lower MOOP amount may use cost sharing up to certain levels for specific services (as identified in § 422.100(j)(1)(i)) as a means of incentivizing use of alternative services or ensuring an overall balance of enrollee payments and plan financial liability for the entire package of basic benefits is competitive and attractive to beneficiaries.

CMS is finalizing the proposal concerning cost sharing for home health benefits – which was generally consistent with current policy – to require MA plans with a mandatory or intermediate MOOP amount to have cost sharing that does not exceed original Medicare for home health, but to permit MA plans with a lower MOOP amount to charge cost sharing up to 20 percent coinsurance with a modification to avoid duplicative language in the regulation. As discussed in a previous response to comment in this section, § 422.100(j)(1)(ii) requires that MA organizations use the average Medicare FFS allowable cost in the plan service area or the estimated total MA plan financial liability for the benefit for that contract year to calculate an actuarially equivalent copayment value to cost sharing under original Medicare, in the absence of a copayment limit calculated by CMS, for benefits subject to paragraph (j)(1). We are finalizing the rule for cost sharing for home health services largely as provided in proposed paragraph (i)(1)(iv) (re-designated to paragraph (j)(1)(i)(D)), with edits to be consistent with paragraph (i)(1)(ii) and to avoid limiting MA organizations to using only the estimated total MA plan financial liability for that contract year to calculate a copayment that is actuarially equivalent to. or less than, 20 percent coinsurance. We note MA organizations may use the total MA plan financial liability to establish a copayment for home health services, as proposed, under the modifications finalized to paragraph (j)(1) if CMS does not set a copayment limit. CMS will continue to review plans' cost sharing amounts to make sure that plan designs are consistent with MA rules, do not impose significant increases in cost sharing or decreases in benefits from the prior contract year, and are not discriminatory.

Comment: A commenter supported our proposal to add home health services and DME to the list of services for which cost sharing charged by an MA plan may not exceed cost sharing required under original Medicare for plans with mandatory and intermediate MOOP limits.

Another commenter noted that although they supported differentiating copayment limits for home health services by the type of MOOP limit, cost sharing limit differentiation for this service category does not equate to much actuarial value for MA plans given its low utilization and stated that many plans do not impose home health copayments, primarily because it is difficult to collect copays, and many home health agencies are not set up to collect cost sharing under Medicare.

Response: We appreciate the commenters' support. We expect differentiating cost sharing limits across highly utilized services (for example, inpatient and primary care) and various other cost sharing services categories (for example, home health) may produce a cumulative incentive for MA plans to use lower MOOP limits. CMS is finalizing the proposals, to codify cost sharing limits for chemotherapy administration services to include chemotherapy drugs and radiation therapy integral to the treatment regimen, dialysis, SNF, home health, and DME service categories at $\S 422.100(j)(1)(i)(A) - (E)$ (proposed in paragraphs (j)(1)(i) - (v)) and (j)(2)(i)(A), (B), and (D) with the modifications discussed in responses to comment in this section.

Comment: A commenter opposed the proposal providing additional flexibility that could increase cost sharing limits for drugs and biologics covered under Part B. The commenter believed maintaining the current upper limits (which have been 20 percent coinsurance or \$50 copayment) protects particular beneficiaries who might be impacted by cost sharing in excess of the amounts established for the original Medicare program.

Response: We thank the commenter for their feedback on our proposal to apply a range of cost sharing limits in § 422.100(f)(6)(iii) for the "Part B drugs – Other" service category. We agree with the commenter, as a result of an analysis of the most recent Medicare FFS data

projections available at the time of this FC, that increasing the cost sharing limits from our longstanding 20 percent coinsurance or \$50 copayment limit to a range of cost sharing limits based on the type of MOOP limit (30, 40, and 50 percent, respectively) in one year would likely result in disruption for enrollees. Using contract year 2023 Medicare FFS data projections (based on 2017 – 2021 Medicare FFS data), the projected total median cost for "Part B drugs – Other" service category equals \$1,603.00 and the weighted average cost equals \$2,437.00 (including drug and related service costs). To calculate a copayment limit for the "Part B drugs – Other" service category at an actuarially equivalent dollar amount to 50 percent using either of these projections when the contract year 2022 limit was 20 percent or \$50 does not adequately protect enrollees from potentially significant changes in costs. While the annual cap on change to copayment limits during the transition to actuarially equivalent values finalized in paragraph (f)(8) (as discussed in section II.B.5.b. of this FC) would help offset the increase in contract year 2023, it would be insufficient to fully protect beneficiaries from the potentially significant changes in their out of pocket costs. This is because despite applying paragraph (f)(8), the coinsurance limit for the "Part B drugs – Other" service category would still increase from 20 percent to 50 percent for MA plans that establish a lower MOOP amount and the associated transitional copayment limit for the lower MOOP type would increase from \$50 to \$240 within one year (based on contract year 2023 Medicare FFS data projections and applying the rounding rules in paragraph (f)(6)(ii)). These increases represent the maximum permissible cost sharing, but not all MA plans may adopt cost sharing at these maximum levels. However, the potential for these increases in cost sharing, particularly a change from current policy for the "Part B drugs - Other' service category, requires us to reconsider this aspect of our proposal.

After consideration of several alternatives as discussed in section V.H.2. of this FC, instead of finalizing this aspect of our proposal, CMS is maintaining and codifying our longstanding 20 percent coinsurance limit for the "Part B Drugs – Other" service category, by adding new § 422.100(j)(1)(i)(F), which adds other drugs covered under Part B of original

Medicare (that is, Part B drugs not included in paragraph (j)(1)(i)(A)) to the list of benefits for which cost sharing must not exceed cost sharing under original Medicare. The use of Part B drugs to treat serious illnesses and the potential for those drugs to be costly likely presents significant potential for discrimination against (or potential for discouraging enrollment by) beneficiaries who have health conditions treated by Part B drugs other than chemotherapy/radiation. We believe that maintaining our long-standing policy of having 20 percent coinsurance and copayment limits for all Part B drugs, in addition to a per member per month actuarially equivalent requirement for the Part B drug service category, protects beneficiaries with high health care needs from benefit designs that discriminate against or discourage enrollment in an MA plan, steer subsets of Medicare beneficiaries to particular MA plans, or inhibits access to services. The language in paragraph (i)(1)(i)(F) is clear that this requirement is separate from the service category specific to Part B chemotherapy drugs and radiation therapy. In comparison, these service categories were combined in our proposal to include "drugs and biologics covered under Part B of original Medicare (including both chemotherapy/radiation drugs integral to the treatment regimen and other drugs covered under Part B)" in paragraph (i)(2). Having coinsurance and copayment limits in addition to a PMPM actuarially equivalent requirement is consistent with our long standing practice and policy for cost sharing for Part B drugs. As a practical matter, in proposing both: (1) applying a range of cost sharing limits to the "Part B drugs – Other" service category; and (2) requiring cost sharing to be actuarially equivalent to Medicare FFS on a PMPM basis for Part B drugs (which is inclusive of the "Part B drugs – Other" service category), the flexibility that seems available by proposing a range of cost sharing limits up to 50 percent coinsurance or actuarially equivalent copayment for this service category is very limited.

Currently, § 422.100(j)(1) requires MA plans to use cost sharing that does not exceed cost sharing in original Medicare for "chemotherapy administration services to include chemotherapy drugs and radiation therapy integral to the treatment regimen;" we proposed to

revise the text to describe these benefits as "chemotherapy administration services to include chemotherapy/radiation drugs integral to the treatment regimen" and to redesignate it as paragraph (j)(1)(i). We are finalizing continued application of this cost sharing limit, but redesignating it as paragraph (j)(1)(i)(A) and refining the text to clarify this limit applies to chemotherapy administration services to include chemotherapy/radiation drugs and radiation therapy integral to the treatment regimen. We are fundamentally maintaining the current regulatory description and aligning the language with the current structure of the PBP (which captures cost sharing information for therapeutic radiological services and chemotherapy/radiation drugs in separate sections). We are not making any changes to our longstanding bid review practices or policies related to this service category by making this change to the name of the benefit in paragraph (j)(1)(i)(A).

As discussed in section II.B.5.b. of this FC, copayment limits set for certain service categories in past years do not reflect current actuarially equivalent values based on 20 percent coinsurance. Rather, our proposed methodology to calculate copayment limits based on values that are actuarially equivalent to the coinsurance limit, will result in recalibration of the copayment limits by applying a methodology adjusted from longstanding policy to the most recent Medicare FFS data projections available. Commenters expressed concerns about potentially significant increases to cost sharing limits within one year, such as for the "physical therapy and speech-language pathology" and "dialysis services" service categories in addition to the "Part B drugs – Other" service category. As discussed in other responses to comment in section II.B. of this FC, CMS agrees with the commenters that the proposed policies can be improved by providing for a transition process to recalibrate copayment limits over time. This transition is also being applied to the "Part B drugs – Other" service category. Specifically, we will transition from the \$50 contract year 2022 copayment limit to an actuarially equivalent value to 20 percent based on the most recent Medicare FFS data projections by contract year 2026 (as finalized in $\S 422.100(i)(1)(ii)$, (f)(7), and (f)(8)). To illustrate the impact of applying an annual

cap on changes to the copayment limits during the actuarially equivalent copayment transition for the "Part B drugs – Other" service category, the calculations to reach the final contract year 2023 copayment limit for the "Part B drugs – Other" service category are provided in Table 25B. As shown in Table 25B, the calculations of the transitional copayment limit for this service category are based on the median Medicare FFS cost projection of \$1,603.00 using contract year 2023 Medicare FFS data projections (based on 2017 – 2021 Medicare FFS data). Using the median amount results in a lower copayment limit than if the weighted average Medicare FFS allowed amount was used; we choose between these actuarial approaches under § 422.100(f)(7)(ii)(C) and were guided by the purposes of the MA program. As part of that, we considered how which approach would most closely reflect an actuarially equivalent copayment for the benefit and beneficiary population, protect against discriminatory cost sharing, and be in the best interests of beneficiaries, including protection against fluctuations in cost sharing or sudden, disruptive increases in cost sharing. In this specific case we believe choosing the lower actuarially equivalent copayment value would better protect beneficiaries from potentially disruptive increases to the cost sharing for that benefit in comparison to prior years. We emphasize that there is significant potential for discrimination against (or potential for discouraging enrollment by) beneficiaries who have health conditions treated by costly Part B drugs. We believe that choosing the lower actuarially equivalent copayment value protects beneficiaries with high health care needs from benefit designs that discriminate against or discourage enrollment in an MA plan, steer subsets of Medicare beneficiaries to particular MA plans, or inhibits access to services.

Row J in Tables 25A and 25B illustrates the comparison CMS will complete after calculating both the actuarially equivalent value to cost sharing under original Medicare and the transitional copayment limit for each service category subject to paragraph (j)(1) during the multiyear transition to actuarially equivalent copayment limits. For example, as shown in row J in Table 25B, the transitional copayment value for contract year 2023 is less than the actuarially

equivalent value compared to cost sharing under original Medicare for the "Part B drugs – Other" service category. As a result of the "lesser of" requirement in paragraph (f)(8), this transitional copayment value from row J in Table 25B is included in Table 28 as the final contract year 2023 copayment limit for this service category. In addition, no transition is being applied to the coinsurance limit for the "Part B drugs – Other" service category because the 20 percent limit has been in place under our current policy since 2012.

We acknowledge that under our final policy, the copayment limit for the "Part B drugs – Other" service category is still increasing from \$50 in contract year 2022 to \$120 for contract year 2023 after incorporating 25 percent of the actuarially equivalent copayment differential in § 422.100(f)(8)(ii)(A) and application of the rounding rules in § 422.100(f)(6)(ii). However, updating the copayment limits to reflect the most recent actuarially equivalent values will address the costs MA organizations are expected to incur in providing these services for MA enrollees and make appropriate adjustments for medical inflation since the current copayment limits were last updated. Currently, the vast majority of MA plans have designed their "Part B drugs – other" benefit with cost sharing greater than zero and use coinsurance rather than a copayment. For contract year 2021 (based on March 2021 plan data) approximately 2 percent of MA and MA-PD plans (excluding employer, D-SNPs, and MSA plans) established a copayment for the "Part B drugs – other" service category (\$50 or greater than zero), suggesting that the upper copayment limits for contract year 2022 may not fully reflect the costs MA organizations are experiencing to cover this benefit for enrollees. This trend of a small percentage of plans offering a copayment has remained relatively consistent since 2012. In 2012, approximately 5 percent of MA and MA-PD plans (excluding employer, D-SNPs, and MSA plans) established a copayment of \$50 or greater than zero for the "Part B drugs – other" service category. Considering the percent of plans and enrollees where coinsurance is equal to original Medicare for the "Part B drugs – other" service category (approximately 97 percent and 93 percent in contract year 2021, respectively), we believe it is persuasive that having a copayment set at an

amount that is less than an actuarially equivalent value to the coinsurance limit does not necessarily result in lower cost sharing, but might encourage plans to use coinsurance instead. The copayment limits for the "Part B Drugs - Other" category set for contract year 2022 have been in place since at least 2012. We expect that this transition to actuarially equivalent values will ultimately result in stable benefit packages by ensuring cost sharing limits are calculated following established actuarial methods, using the most recent Medicare FFS data projections available, and by keeping copayment limits aligned with coinsurance limits. CMS will track cost sharing changes for the "Part B drugs – Other" service category and pursue future rulemaking, if appropriate. For example, we will continue to review the projected weighted average and median Medicare FFS allowed amounts from the OACT annually, consult with the OACT on whether any applicable cost trends are expected to be consistent for future contract years, and consider how market competition or payment policies may affect or necessitate changes to the methodology CMS used to calculate cost sharing limits finalized here.

f. Per Member Per Month Actuarial Equivalent (AE) Cost Sharing Limits For Basic Benefits (§ 422.100(j)(2))

Comment: A few commenters generally supported CMS's proposals (in section VI.B.4. of the February 2020 proposed rule) to require cost sharing for specific categories of basic benefits that does not exceed cost sharing in original Medicare on per member per month actuarially equivalent basis. These commenters also requested clarifications or modifications on these proposals as summarized in this section, which would be codified at § 422.100(j)(2). A commenter questioned whether CMS adjusted the calculations and methodology used to compare per member per month plan cost sharing to the adjusted original Medicare actuarially equivalent cost sharing to account for the impact of beneficiaries with diagnoses of ESRD enrolling in the MA program beginning in contract year 2021 as a result of the 21st Century Cures Act. In addition, the commenter requested that CMS clarify how the plan level inpatient calculations and limits for per member per month actuarially equivalent cost sharing are

impacted by the projected increase to inpatient hospital acute and psychiatric services cost sharing limits based on CMS's proposal to transition ESRD costs into the methodology used to set limits for that service category.

Response: We thank the commenters for their support and feedback on our proposals related to per member per month actuarially equivalent cost sharing limits for basic benefits. We are finalizing § 422.100(j)(2) generally as proposed, with modifications to ensure clarity in the regulations (as discussed in each response to comment in this section). We generally proposed to codify the longstanding policy that MA cost sharing for all basic benefits and certain categories of basic benefits must not exceed the cost sharing in original Medicare on a per member per month actuarially equivalent basis. This determination of per member per month actuarial equivalence is how the OACT currently evaluates the requirement in § 422.254(b)(4) and section 1852(a)(1)(B) of the Act that MA plans must cover Part A and B benefits (subject to exclusions for hospice benefits and costs for kidney acquisitions for transplants) with cost sharing for those services at least as required under Part A and B or an actuarially equivalent level of cost sharing. We are modifying the heading of paragraph (j)(2) to clarify that (j)(2) is an evaluation of all basic benefits and specific categories of basic benefits in the aggregate. For example, paragraph (i)(1) addresses the cost sharing limit applicable to each service category of DME and paragraph (i)(2) addresses the overall evaluation of the DME benefit category (the aggregate of all DME service categories). As with all MA requirements, § 422.100(j)(2) applies as well to employer plans unless there is a waiver provided by CMS under section 1857(i) of the Act. (Generally, all MA plans must comply with the cost sharing and MOOP limits adopted by this FC except for MA MSA plans because MA MSA plans must not cover basic benefits under the plan's deductible has been reached and after the deductible is reached, the plan must cover 100 percent of the costs of basic benefits. See section 1859(b)(3) of the Act and § 422.4(a)(2).) This includes both the aggregate and service-category specific PMPM actuarially equivalent requirements in paragraph (i)(2). As proposed and finalized in paragraph (i)(2), this requirement that cost sharing

for basic benefits not exceed cost sharing in original Medicare does not apply to out-of-network benefits for a regional MA plan; this is consistent with section 1852(a)(1)(B)(ii).. We proposed and are finalizing a longstanding bid evaluation of per member per month actuarial equivalence (rather than a specific cost sharing limit).

As finalized, § 422.100(j)(2)(i)(A) includes a clarification in the definition and scope of inpatient hospital acute and psychiatric services to which the PMPM limit will apply. For this regulation, "inpatient hospital acute and psychiatric services" means services provided during a covered inpatient stay during the period for which cost sharing would apply under original Medicare. We are not finalizing the reference to an inpatient facility as we believe individuals could interpret the word facility in a stricter fashion than how this category is reviewed for the PMPM evaluation. As finalized, the regulation is consistent with how CMS has completed the PMPM evaluation in longstanding practice and with section 1852(a)(1)(B)(ii) of the Act (85 FR 9087).

As part of the annual release of subregulatory guidance under new § 422.100(f)(7)(iii), CMS intends to issue instructions describing how excess cost sharing is evaluated using bid pricing tool (BPT) information to satisfy the per member per month actuarially equivalent requirement for the benefit categories subject to § 422.100(j)(2) (including inpatient). We include instructions for contract year 2023 in this section of this FC and will issue instructions for future contract years through annual subregulatory guidance. The approach evaluating compliance with the per member per month limits uses information specific to each MA plan bid and will happen during CMS review of bids consistent with longstanding practice. We are codifying this evaluation to protect beneficiaries against discriminatory cost sharing. The per member per month actuarial equivalence factors for the Inpatient and SNF benefit categories had historically included costs from beneficiaries with diagnoses of ESRD. A correction was made beginning for contract year 2021 bids to exclude costs from beneficiaries with diagnoses of ESRD in order to be consistent with the treatment of ESRD in the BPT. ESRD costs are

excluded since the bid development is for the non-ESRD population to correspond with payment policy. Although the limits on eligibility for MA plan enrollment by beneficiaries with ESRD diagnoses were removed beginning for contract year 2021, ESRD utilization and payment information is different, when compared to other enrollees, and CMS will continue to exclude these factors from the primary pricing sections of the MA BPT. Additionally, the Medicare FFS Actuarial Equivalent Cost Sharing Factors in the MA BPT are calculated excluding ESRD utilization and payment information because the pricing in the bid is for the non- ESRD population. Therefore, in response to the commenter's question on whether the calculations and methodology used to compare per member per month plan cost sharing to the adjusted original Medicare actuarially equivalent cost sharing was modified to account for the impact of beneficiaries with diagnoses of ESRD enrolling in the MA program beginning in contract year 2021 as a result of section 17006 of the 21st Century Cures Act, we note that the evaluations and analyses to determine compliance with § 422.100(i)(2) will not include beneficiaries with diagnoses of ESRD in the development of the adjustment factors that account for physician allowed costs and cost sharing for the Inpatient and SNF benefit categories subject to § 422.100(j)(2). This approach does not have a material impact on MA plans being able to meet the Inpatient hospital and SNF cost sharing PMPM actuarial equivalence evaluation and is consistent with how information is collected in the BPT. The actuarially equivalent cost sharing factors used in the MA BPT exclude enrollees in ESRD status, as does the projection of bid expenditures. That is, MA organizations are paid the full risk-adjusted benchmark rate for ESRD enrollees and ESRD enrollees are excluded from the BPT and benchmark projections. In order to account for the projected marginal costs (or savings) of enrollees in ESRD status (as referenced in BPT instructions) the BPT allows for an adjustment that is allocated across ESRD and non-ESRD members (including out-of-area members).

In response to the request for clarity about the impact of the ESRD cost transition on the Inpatient hospital PMPM actuarial equivalence evaluation required by § 422.100(j)(2)(i)(A), we

note that the PMPM actuarial equivalence evaluation is separate from and is conducted differently than evaluating the MA cost sharing standards. Both evaluations are used to protect against benefit designs that discriminate against and discourage enrollment by beneficiaries with a health status that requires those services. The per member per month actuarial equivalence evaluation uses BPT data in four service categories (Inpatient, SNF, DME, and Part B drugs) in a manner consistent with the BPT data collection that excludes ESRD costs. The BPT is used for establishing payments for non-ESRD enrollees, while payments for ESRD enrollees are based on the ESRD ratebook. The service category cost sharing standards adopted in this rule (at § 422.100(f)(6)(iv)) for inpatient scenarios and (at § 422.100(f)(6)(i) and (iii) and (j)(1)) for other basic benefits are based on enrollee cost sharing entered in the PBP and includes cost sharing for all beneficiaries, including those with diagnoses of ESRD. Benefits and cost sharing must be uniform for all MA plan enrollees, or similarly situated enrollees⁵⁹ pursuant to existing regulations that are not being changed. As discussed in several other responses in this FC, payment by CMS to MA plans for coverage of enrollees with ESRD is, consistent with section 1853(a)(1)(H) of the Act, not the same as payment to MA plans for other enrollees.

Comment: As summarized in section II.B.5.e., a commenter opposed the proposal providing additional flexibility that could increase cost sharing limits for drugs and biologics covered under Part B. This commenter also supported CMS's proposal (in § 422.100(j)(2)(i)(C)) to codify existing policy regarding the specific benefit categories for which MA plans must not exceed the cost sharing in original Medicare on a per member per month actuarially equivalent basis, including drugs and biologics covered under Part B of original Medicare (including both chemotherapy/radiation drugs and other drugs covered under Part B). Specifically, this commenter supported CMS maintaining the current upper limits for Part B drug cost sharing to help ensure that cost sharing is not discriminatory. This commenter did not want this category to

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⁵⁹ Except in the case of special supplemental benefit for the chronically ill (SSBCI) offered in accordance with § 422.102(f), in which CMS may waive uniformity requirements in connection with providing SSBCI to eligible chronically ill enrollees.

be modified to provide any additional flexibility that could increase cost sharing limits for drugs and biologics covered under Part B. The commenter supported CMS continuing to set specific cost sharing limits for individual service categories (including Part B drug cost sharing) based on the belief that maintaining these upper limits protects beneficiaries who might be impacted by cost sharing in excess of the amounts established for the original Medicare program.

Response: We thank the commenter for their feedback on our proposal to codify the current requirement that cost sharing for Part B drugs and biologics must not exceed cost sharing for that benefit category in original Medicare on a PMPM actuarially equivalent basis. We are finalizing this proposal with modification to clarify that cost sharing in MA plans must not exceed the cost sharing in original Medicare on a per member per month actuarially equivalent basis for all drugs and biologics covered under Part B of original Medicare. CMS is not finalizing the proposed language referencing both chemotherapy/radiation drugs integral to the treatment regimen and other drugs covered under Part B in § 422.100(j)(2)(i)(C) because that text is unnecessary. This change simplifies the regulation and more accurately reflects the breadth of drugs that are applicable to paragraph (j)(2)(i)(C). These changes do not impact how CMS conducts the PMPM actuarial equivalence evaluation for any benefit category. In respect to the comments related to providing additional flexibility that could increase cost sharing limits for drugs and biologics covered under Part B, we address these concerns in section II.B.5.e. of this FC.

Comment: A commenter recommended that CMS broaden the benefit categories listed in proposed § 422.100(j)(2) to include home health and physical therapy services to protect beneficiaries from excessive cost sharing for those services.

Response: We appreciate the commenter's request to add physical therapy and home health to the list of service categories in § 422.100(j)(2) for which an MA plan may not exceed cost sharing required under original Medicare on a per member per month actuarially equivalent basis, but we are not adopting such a change. The BPT categories typically include multiple PBP

service categories and may not collect details necessary to evaluate a specific specialty category on the basis of per member per month actuarial equivalence; this is the case for physical therapy, for example. We will consider future revisions to the PBP and/or BPT to gather more information and will pursue future rulemaking, if appropriate.

CMS's longstanding policy has been to allow MA plans to establish up to 50 percent coinsurance or an actuarially equivalent copayment for in-network professional services except for those services for which cost sharing cannot exceed original Medicare, regardless of the MOOP type (including cost sharing for physical therapy). In this FC, we are limiting, subject to a transition period, this flexibility to MA plans that establish a lower MOOP amount. We also note a more complete discussion related to CMS's considerations of changing our longstanding policy to limit certain cost sharing flexibilities to MA plans that establish a lower MOOP amount is provided in section II.B.5.b. of this FC. As discussed in section II.B.5.b. of this FC, in response to comments specifically about physical therapy, the provisions we proposed and are finalizing ensure that, beginning with contract year 2023, MA plans always pay at least 50 percent of the estimated total financial liability (for plans with a lower MOOP amount) and a higher percentage for those services in plans that establish an intermediate or mandatory MOOP amount than in prior contract years.

We believe the cost sharing standards we are finalizing in § 422.100(f)(6)(iii) for physical therapy and in § 422.100(j)(1)(i)(D) for home health will adequately protect beneficiaries from discriminatory cost sharing with regard to those services. Because original Medicare has no cost sharing for home health, it would be difficult to apply the PMPM actuarial equivalence evaluation in paragraph (j)(2) to this service category. The highest allowable MA plan cost sharing limit for home health is 20 percent or an actuarially equivalent copayment (including a copayment limit calculated by CMS as discussed in sections II.B.5.a., b., and e. of this FC) which is limited to MA plans with a lower MOOP amount. MA plans that establish a mandatory or intermediate MOOP amount must establish \$0 cost sharing for home health services under the

provision we are finalizing in § 422.100(j)(1)(i)(D) (proposed in paragraph (j)(1)(iv)). CMS will continue to evaluate MA plans during bid review in relation to these cost sharing categories and will pursue future rulemaking to address any concerns, if appropriate.

We are finalizing $\S 422.100(j)(2)(ii)$ generally as proposed, but with modifications to: (1) correct the reference to generally accepted actuarial principles and practices (rather than only principles) in the regulation; (2) clarify the requirements in paragraph (j)(2)(i) apply to the MA plan's cost sharing for all for basic benefits and specific categories of basic benefits, rather than specific services; and (3) clarify that CMS may extend flexibility regarding compliance with the requirements in paragraph (j)(2)(i) to an MA plan that has excess cost sharing (meaning the PMPM actuarial value of the plan's cost sharing is higher than the PMPM actuarial value of the cost sharing in original Medicare) to the extent that it is actuarially justifiable and provided that certain conditions are met. Specifically, the MA plan's cost sharing must be based on generally accepted actuarial principles and practices (consistent with paragraph (f)(7)) and supporting documentation included in the bid, and the MA plan's cost sharing must otherwise comply with applicable cost sharing standards. We anticipate this exception would apply in limited situations, such as when the MA plan uses capitated arrangements with provider groups, operates their own facilities, or other unique arrangements. This flexibility is consistent with long-standing policy and practice.

We are finalizing in § 422.100(j)(2), with the modifications discussed previously in this section, our proposals to impose requirements related to the per member per month (PMPM) actuarial value of the cost sharing for basic benefits. As a result, for contract year 2023 and subsequent years, CMS will separately evaluate the PMPM actuarial value of the cost sharing used by each MA plan for the following service categories: Inpatient, Skilled Nursing Facility (SNF), Durable Medical Equipment (DME), and Part B drugs. Whether in aggregate, or on a service-specific basis, this evaluation is done by comparing two values in the plan's BPT. In essence, CMS compares the actuarial value of a plan's PMPM cost sharing for the benefit

category to the estimated actuarial value of original Medicare cost sharing for the same benefit category in order to determine plan compliance. Specifically, for contract year 2023, a plan's PMPM cost sharing for Medicare covered services (BPT Worksheet 4, Section IIA, column 1) will be compared to Medicare covered actuarially equivalent cost sharing (BPT Worksheet 4, Section IIA, column n). For Inpatient hospital and SNF services, the Medicare actuarially equivalent cost sharing values, unlike plan cost sharing values, do not include Part B cost sharing. Therefore, an adjustment factor is applied to these Medicare actuarially equivalent values to incorporate Part B cost sharing and to make the comparison valid. CMS annually updates and communicates the Part B adjustment factors prior to bid submission. Please note that factors for Inpatient and Skilled Nursing Facility in column #4 of Table 27 (Part B Adjustment Factor to Incorporate Part B Cost Sharing) have been updated for contract year 2023. Once the comparison amounts have been determined, CMS can evaluate excess cost sharing. Excess cost sharing is the difference (if positive) between the plan cost sharing amount (column #1 in Table 27) and the comparison amount in column #5 of Table 27 (which reflects an estimated original Medicare cost sharing which is weighted based on the plan's projected county enrollment). This evaluation process remains consistent with prior years. 60 Table 27 uses illustrative values to demonstrate the mechanics of this determination for contract year 2023. We also note that, beginning in contract year 2017, CMS waived the requirement, under section 1857(i) of the Act, for MA employer plans (EGWPs) to submit a BPT, which affects our ability to evaluate EGWPs on the PMPM Actuarial Equivalent Cost Sharing standards discussed in this section. MA EGWPs continue to be subject to all MA regulatory requirements that have not explicitly been waived by CMS, including the cost sharing requirements we are finalizing in § 422.100(j)(2),

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⁶⁰ For information on per member per month actuarial equivalent cost sharing bid review criteria in contract year 2021 and 2021, see the HPMS memorandum titled "Final Contract Year 2021 Part C Benefits Review and Evaluation," issued April 8, 2020 for contract year 2021 and the HPMS memorandum titled "Final Contract Year 2022 Part C Benefits Review and Evaluation," issued May 20, 2021 for contract year 2022.

regardless of whether they are affirmatively evaluated as part of bid review or in connection with other reviews.

TABLE 27: ILLUSTRATIVE COMPARISON OF SERVICE-LEVEL ACTUARIAL EQUIVALENT COSTS TO IDENTIFY EXCESSIVE COST SHARING FOR CONTRACT YEAR 2023

	#1	#2	#3	#4	#5	#6	#7
ВРТ	PMPM Plan Cost Sharing (Parts A&B)	Medicare FFS Allowed Amount	Medicare FFS Actuarially Equivalent Cost Sharing	Part B Adjustment Factor to Incorporate Part B Cost Sharing (Based on Medicare FFS	Comparison Amount ²	Excess Cost Sharing	
Benefit		(BPT		Data		(#1 – #5,	
Category	(BPT Col. l)	Col. m)	(BPT Col. n) 1	Projections)	(#3 × #4)	min of \$0)	Pass/Fail
Inpatient	\$33.49	\$331.06	\$25.30	1.362	\$34.46	\$0.00	Pass
SNF	\$10.83	\$58.19	\$9.89	1.083	\$10.71	\$0.12	Fail
DME	\$3.00	\$11.37	\$2.65	1	\$2.65	\$0.35	Fail
Part B-Rx	\$0.06	\$1.42	\$0.33	1	\$0.33	\$0.00	Pass

¹ PMPM values in column #3 for Inpatient and SNF only reflect Part A FFS actuarial equivalent cost sharing for that service category.

CMS will, as described in new § 422.100(f)(7)(iii) (and previously discussed in section II.B.5.a. of this FC), issue subregulatory guidance for contract year 2024 and future years prior to bid submission to allow sufficient time for MA organizations to prepare and submit plan bids. This guidance will include how CMS will evaluate compliance with § 422.100(j)(2) and identify excessive cost sharing. The information will be consistent with prior years⁶¹ and may be shared through publicly-available HPMS memoranda.⁶² Consistent with prior practice (for example, the HPMS memorandum addressing MOOP and cost sharing standards for contract year 2022), CMS may avoid repeating guidance that is unchanged from the prior year. For example, if the per member per month evaluation will be conducted in the same manner as the prior contract year and was sufficiently explained in the prior year's guidance or within this FC, we may only

² Estimated original Medicare cost sharing weighted based on the plan's projected county enrollment.

⁶¹ See Table 4: Illustrative Comparison of Service-Level Actuarial Equivalent Costs to Identify Excessive Cost Sharing in the HPMS memorandum titled "Final Contract Year 2021 Part C Benefits Review and Evaluation" issued April 8, 2020 for an example.

⁶² Individuals and organizations may request placement on a listsery at https://hpms.cms.gov/app/ng/home/ to receive future HPMS memoranda.

cite to the prior year's communications, summarize, or highlight information that has changed to streamline annual guidance.

g. In-Network Service Category Cost Sharing Requirements

Comments received on section VI.B.3.d. from the February 2020 proposed rule were summarized and responded to in sections II.B.5.a. – f. of this FC. Table 28 provides a summary of final contract year 2023 in-network service category cost sharing limits based on the finalized policies discussed in section II.B.5.a. – f. of this FC. This table is an updated version of Table 5 (Illustrative Contract Year 2022 In-Network Service Category Cost Sharing Limits) from section VI.B. of the February 2020 proposed rule. Some of the changes, in comparison to Table 5 from the February 2020 proposed rule, are a result of various factors: (1) using the more recent Medicare FFS beneficiary data projections available at the time of this FC; (2) applying the updated ESRD cost transition schedule finalized at § 422.100(f)(4)(vii) for inpatient hospital cost sharing limits (and for MOOP limits where the MOOP limit amount restricts the available cost sharing); (3) applying the cost sharing limit transition provisions (finalized at $\S\S$ 422.100(f)(6), (f)(8), and 422.113(b)(2)(v)) for professional services, benefits for which cost sharing must not exceed cost sharing under original Medicare, and emergency services; (4) calculating the actuarially equivalent copayment limits for the "primary care physician" and "physician" specialist" service categories based on the revised group of provider specialties discussed in section II.B.5.b. in this FC; and (5) applying the requirement finalized at § 422.100(j)(1)(i)(F) that MA plans must not use cost sharing that exceeds cost sharing in original Medicare for Part B drugs other than the specific drugs listed in paragraph (j)(1)(i)(A). In addition, we updated prior "N/A" designations for certain service categories as discussed in section II.B.5.a. and c. of this FC and the footnotes for clarity and to reflect the finalized policies.

As discussed in the February 2020 proposed rule, CMS will annually update the cost sharing limits, using the methodology adopted in this FC (at §§ 422.100(f)(4) through (f)(8), 422.100(j), and 422.113(b)(2)) to calculate and issue the cost sharing limits each year. As this

FC is being published in advance of the bidding deadline for contract year 2023 and with the availability of contract year 2023 Medicare FFS data projections, the contract year 2023 cost sharing limits in Table 28 are final. In addition, CMS will calculate updated limits for contract year 2024 and future years based on more recent Medicare FFS data projections from the OACT and the methodology finalized through this FC. As a result, in-network service category cost sharing limits for contract year 2024, as well as subsequent years, will be issued annually using a subregulatory guidance process that includes an opportunity for comment, as finalized in paragraph (f)(7)(iii).

Except for the requirement in § 422.100(f)(6)(i) that MA plans pay at least 50 percent of estimated total MA financial liability for basic benefits, even when furnished out of network, the standards in Table 28 only apply to in-network Parts A and B services. All standards and cost sharing are inclusive of applicable service category deductibles, copayments and coinsurance, but do not include plan level deductibles (for example, deductibles that include several service categories). Together, the per member per month actuarial equivalence evaluation and the Part C service category cost sharing standards make sure that benefit designs are not discriminatory to beneficiaries based on health status.

TABLE 28: FINAL CONTRACT YEAR 2023 IN-NETWORK SERVICE CATEGORY COST SHARING LIMITS USING PROJECTIONS OF 2017 – 2021 MEDICARE FFS DATA

	PBP Section B Data Entry		Intermediate	Mandatory
Service Category	Field	Lower MOOP	MOOP	MOOP
Inpatient Hospital – Acute - 60 days ¹	1a	\$3,650	\$4,690	\$5,729
Inpatient Hospital – Acute - 10 days ¹	1a	\$3,124	\$2,812	\$2,499
Inpatient Hospital – Acute - 6 days ¹	1a	\$2,801	\$2,521	\$2,241
Inpatient Hospital – Acute - 3 days ¹	1a	\$2,562	\$2,306	\$2,050
Inpatient Hospital Psychiatric - 60 days ¹	1b	\$3,650	\$3,325	\$3,000
Inpatient Hospital Psychiatric - 15 days ¹	1b	\$2,530	\$2,277	\$2,024
Inpatient Hospital Psychiatric - 8 days ¹	1b	\$2,340	\$2,106	\$1,872
Skilled Nursing Facility – First 20 Days ^{2,3}	2	\$20/day	\$10/day	\$0/day
Skilled Nursing Facility – Days 21 through 100 ^{2,3}	2	\$196/day	\$196/day	\$196/day
Cardiac Rehabilitation ^{4,5}	3	50% / \$40	47% / \$40	45% / \$40
Intensive Cardiac Rehabilitation ^{4,5}	3	50% / \$65	47% / \$60	45% / \$60
Pulmonary Rehabilitation ^{4,5}	3	50% / \$20	47% / \$20	45% / \$20
Supervised exercise therapy (SET) for Symptomatic peripheral artery disease (PAD) ⁴	3	50% / \$30	47% / \$30	45% /\$25
Emergency Services ^{4,6}	4a	\$125	\$110	\$95
Urgently Needed Services ^{4,6}	4b	50% / \$65	47% / \$60	45% / \$60
Partial Hospitalization ⁴	5	50% / \$75	47% / \$70	45% / \$60

	PBP Section B Data Entry		Intermediate	Mandatory
Service Category	Field	Lower MOOP	MOOP	MOOP
Home Health ²	6a	20% / \$404	\$0	\$0
Primary Care Physician ⁴	7a	50% / \$40	47% / \$40	45% / \$35
Chiropractic Care ⁴	7b	50% / \$20	47% / \$20	45% / \$20
Occupational Therapy ⁴	7c	50% / \$45	47% / \$40	45% / \$40
Physician Specialist ⁴	7d	50% / \$60	47% / \$55	45% / \$50
Mental Health Specialty Services ⁴	7e	50% / \$50	47% / \$45	45% / \$40
Psychiatric Services ⁴	7h	50% / \$50	47% / \$45	45% / \$40
Physical Therapy and Speech-language Pathology ⁴	7i	50% / \$50	47% / \$50	45% / \$45
Therapeutic Radiological Services ^{2,4}	8b	20% / \$65	20% / \$65	20% / \$65
DME-Equipment ⁷	11a	50%	50%	20%2,4
DME-Prosthetics ⁷	11b	50%	50%	20%2,4
DME-Medical Supplies ⁷	11b	50%	50%	20%2,4
DME-Diabetes Monitoring Supplies	11c	50% / \$20	50% / \$20	20% / \$10 ^{2,4}
DME-Diabetic Shoes or Inserts	11c	50% / \$25	50% / \$25	20% / \$10 ^{2,4}
Dialysis Services ^{2,4}	12	20% / \$40	20% / \$40	20% / \$40
Part B Drugs-Chemotherapy/Radiation ^{2,4}	15	20% / \$125	20% / \$125	20% / \$125
Part B Drugs-Other ^{2,4}	15 MOOD II : i	20% / \$120		20% / \$120

¹ All MA plans are required to establish cost sharing that does not exceed the plan's MOOP limit or overall cost sharing for inpatient benefits in original Medicare on a per member per month actuarially equivalent basis.

MA plans may not charge enrollees higher costs sharing than is charged under Original Medicare for COVID-19 testing and testing-related services identified in section 1833(cc)(1) for which payment would be payable under a specified outpatient payment provision described in section 1833(cc)(2) during the period from March 18, 2020 through to the end of the emergency period described in section 1135(g)(1)(B), pursuant to amendments to section 1852 of the Act, as amended by the Families First Coronavirus Response Act. We have not incorporated that cost sharing limit into Table 28 because of the time-limited nature of the requirement. However, MA

²MA plans (per § 422.100(j)(1)) and 1876 Cost Plans (per § 417.454(e)) may not charge enrollees higher cost sharing than is charged under original Medicare for Part B chemotherapy administration services, including chemotherapy drugs and radiation therapy integral to the treatment regimen, skilled nursing care, and renal dialysis services. As finalized, MA plans (§ 422.100(j)(1)(i)(F)) may not charge enrollees higher cost sharing than is charged under Original Medicare for "Part B drugs – Other." MA plans that establish a lower MOOP limit may charge cost sharing for home health, while plans with an intermediate or mandatory MOOP must not charge higher cost sharing than in original Medicare (§ 422.100(j)(1)(i)(D)). MA plans that establish a mandatory MOOP limit may also not charge enrollees higher cost sharing than is charged under original Medicare for DME service categories (§422.100(j)(1)(i)(E)).

³ MA plans that establish a lower or intermediate MOOP limit may have cost sharing for the first 20 days of a SNF stay (§ 422.100(j)(1)(i)(C)). The per-day cost sharing for days 21 through 100 must not be greater than one eighth of the projected (or actual) Part A deductible amount, per § 422.100(j)(1)(i)(C)(1). The SNF copayment limit for days 21 through 100 is based on $1/8^{th}$ of the projected Part A deductible for 2023. Total cost sharing for the overall SNF benefit must be not be greater than the actuarially equivalent cost sharing in original Medicare, pursuant to section 1852(a)(1)(B) of the Act, and § 422.100(j)(1)(i)(C).

⁴Cost sharing limits for these service categories (and the mandatory MOOP type for the DME service categories) are subject to the multiyear transition schedules finalized in §§ 422.100(f)(6)(iii), (f)(8), (j)(1), and 422.113(b)(2)(v). In addition, the copayment limits for the primary care physician and physician specialist service categories reflect the change in applicable provider specialties used to calculate the actuarially equivalent copayment value, as described in section II.B.5.b. of this FC.

⁵ The copayment limit set for these service categories reflect application of the "lesser of" requirement in § 422.100(f)(8); the actuarially equivalent value to the coinsurance limit for contract year 2023 is less than the value resulting from the actuarially equivalent copayment transition (after application of the rounding rules).

⁶The dollar amount for Emergency Services and Urgently Needed Services included in the table represents the maximum cost sharing permitted per visit (copayment or coinsurance) and the cost sharing limit applies whether the services are received inside or outside the MA organization, per § 422.113(b)(2)(i), (v), and (vi). Emergency and Urgently Needed Services benefits are not subject to plan level deductible amount and/or out-of-network providers. In addition, the cost sharing limit for Urgently Needed Services is based on the limits specified for professional services in § 422.100(f)(6)(iii) (which includes being subject to the transition limits in § 422.100(f)(8)), as finalized in § 422.113(b)(2)(vi).

⁷For contract years where CMS has not calculated an actuarially equivalent copayment limit, MA plans may establish cost sharing at or less than either (i) the coinsurance limits or (ii) the dollar value that is actuarially equivalent to the coinsurance limit based on their estimated total MA plan financial liability for the benefit for that contract year or the average Medicare FFS allowable amount for the benefit in the plan's service area, as applicable, under § 422.100(f)(6)(i), (iii), and (j)(1).

organizations must comply with it and other statutory cost sharing limits, such as the requirement that cost sharing must not exceed cost sharing in Original Medicare for a COVID-19 vaccine and its administration described in section 1861(s)(10)(A) of the Act, regardless whether CMS specifically addresses such limits when issuing the cost sharing limits calculated annually under §§ 422.100(f) and (j) and 422.113(b)(2).

h. Out-of-Scope Comments

Comment: A few commenters also provided feedback that was outside the scope of the cost sharing limit changes proposed for §§ 422.100 and 422.113 in section VI.B of the February 2020 proposed rule. These commenters requested CMS change ESRD payments for MA plans in addition to, or in place of, transitioning ESRD costs into the data used to set cost sharing limits and raising cost sharing limits. Commenters were concerned that payment changes were needed in order to ensure MA plans and ultimately providers have the resources needed to treat this chronically ill patient population, support MA plans that must cover the higher costs of beneficiaries with diagnoses of ESRD, and prevent detrimental changes to plan options, premiums, cost sharing, and supplemental benefits.

Response: We direct commenters to the two most recent Rate Announcements (Calendar Year 2021 and 2022) at https://www.cms.gov/Medicare/Health-

<u>Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents</u> \for a discussion of MA program payment policies.

6. Final Decision

We received feedback from 17 commenters pertaining to the proposal for setting cost sharing limits, with the majority providing general support, suggested clarifications, or concerns about certain elements of the proposed amendments to §§ 422.100(f)(6), 422.100(j)(1) and (2), and 422.113(b)(2). We thank commenters for their input in helping to inform our final policy concerning cost sharing limits. We are soliciting comments to potentially inform future rulemaking on cost sharing limits as discussed in section III of this FC.

After careful consideration of all the comments we received, and for the reasons set forth in the February 2020 proposed rule and in our responses to the related comments discussed previously, we are finalizing the proposals to amend §§ 422.100(f)(6), 422.100(j)(1) and (2), and 422.113(b)(2) with some modifications and additional provisions to: (1) delay the beginning of implementation of the cost sharing policies by one year; (2) codify the long-standing policy that MA plans must not charge cost sharing that exceeds 50 percent coinsurance or an actuarially equivalent copayment, regardless of the MOOP limit established, for basic benefits (identified within the PBP service category or a reasonable group of benefits or services) that are provided in-network and out-of-network that are not explicitly addressed in § 422.100(f)(6), (j)(1), or § 422.113(b)(2); (3) codify, with some updates and changes, the current process for calculating non-discriminatory cost sharing limits, taking into account ESRD costs; (4) apply a multiyear transition to calculate cost sharing limits for professional services (furnished on an in-network basis based on the MOOP limit established by the MA plan), emergency services, and benefits for which cost sharing must not exceed cost sharing under original Medicare; (5) codify, with some updates and changes (including applying the revised multiyear transition of ESRD costs finalized in section II.A. of this FC), the methodology used to calculate the cost sharing standards for inpatient hospital acute and psychiatric services; (6) set specific cost sharing requirements for emergency services; (7) apply the range of cost sharing limits calculated for professional services to the urgently needed services category; (8) codify that MA plans must not impose cost sharing that exceeds original Medicare for certain specific benefits in addition to the current list in § 422.100(i); (9) codify the cost sharing under original Medicare (20 percent coinsurance) as a cost sharing limit for the "Part B drugs – Other" service category; (10) codify the requirement that total MA cost sharing for all basic benefits and for certain categories of benefits must not exceed cost sharing for those benefits in original Medicare on a per member per month actuarially equivalent basis; (11) provide that an MA plan must not charge an enrollee a copayment for a basic benefit that is greater than the cost of the covered service(s); (12)

provide for an subregulatory comment period for how these regulations are applied for annual cost sharing limits beginning for contract year 2024; and (13) codify the use of generally accepted actuarially principles and practices in applying the MOOP and cost sharing limit regulations. These provisions are applicable for coverage beginning January 1, 2023 and later. We will therefore use these rules and the final contract year 2023 cost sharing limits in Table 28 to evaluate MA bids submissions due the first Monday in June (June 6, 2022) for the 2023 contract year. We will also use these rules to evaluate MA bid submissions for subsequent contract years going forward. In summary, the proposed changes to §§ 422.100(f)(6), 422.100(j)(1) and (2), and 422.113(b)(2) are being finalized substantially as proposed with the following modifications from the proposal:

- The methodology for calculating cost sharing limits in the amendments to §§ 422.100(f), (j), and 422.113(b)(2)(vi) and the specific cost sharing limits in § 422.113(b)(2)(v) are applicable beginning on or after January 1, 2023 instead of January 1, 2022.
- Adding descriptive headings to paragraphs in § 422.100(f)(6) and (j)(1)–(2) to orient the reader to the content in each paragraph.
- Revising § 422.100(f) and (j) to use consistent language in regulation text when referring to: (1) a cost sharing requirement that the MA plan "must", not "may", follow; (2) out-of-pocket costs "incurred by" beneficiaries with and without diagnoses of ESRD; (3) "service categories" instead of "services" or "items"; (4) cost sharing limits "calculated" by CMS by applying these regulations; and (5) cost sharing "established" by MA plans as part of their benefit designs.
- Revising introductory language in § 422.100(f)(6) to: (1) clarify that the cost sharing limits (coinsurance or copayments) are calculated at the plan benefit package service category level or for a reasonable group of benefits covered under the plan; (2) add references to §§ 422.100(j) and 422.113(b)(2), to encompass the cost sharing requirements that apply in those

sections; (3) clarify that § 422.254(b)(4) requires that overall MA cost sharing for basic benefits be actuarially equivalent to, or less than, Medicare FFS cost sharing; (4) clarify that cost sharing evaluations will be completed at the plan (or segment) level; and (5) codify the requirement that an MA plan must not charge an enrollee a copayment for a basic benefit that is greater than the cost of the covered service(s).

- Consolidating the requirements in § 422.100(f)(6)(i)(A), (B), and (C) into one regulatory paragraph at (f)(6)(i) with revisions to: (1) clarify the requirements MA plans must follow to establish a cost sharing amount for service categories subject to paragraph (f)(6)(i); (2) specify the data MA plans must use to determine that its copayment amount for a service category or for a reasonable group of benefits in the PBP does not exceed an actuarially equivalent value to 50 percent coinsurance; (3) clarify that the copayment limits calculated by CMS take precedence; (4) add references to other applicable regulations to clarify the scope of the requirements in paragraph (f)(6)(i); and (5) generally simplify and clarify regulation text.
- Adding language to \S 422.100(f)(6)(ii) to: (1) clarify that CMS will apply the same rounding methodology when calculating copayment limits and evaluating MA plan compliance with paragraphs (f)(6), (f)(7), (f)(8), and (j)(1); and (2) reorganize the regulation text to apply the rounding rules when MA organizations calculate actuarially equivalent values and to increase clarity.
- Revising § 422.100(f)(6)(ii)(A) to add references to paragraphs (f)(6)(i), (f)(6)(iii), and (j)(1) to apply the \$5 rounding methodology consistently to cost sharing limits for professional services and benefits for which cost sharing must not exceed cost sharing under original Medicare.
- Moving the rule for rounding inpatient hospital acute and psychiatric and skilled nursing facility cost sharing limits from § 422.100(f)(6)(ii)(A) to § 422.100(f)(6)(ii)(B) and adding references to paragraphs (f)(6)(iv) and (j)(1)(i)(C) to clarify the regulations that govern the methodology to calculate cost sharing limits for those service categories.

- Moving the rule for rounding copayments when a copayment limit is projected to be exactly between two increments from proposed paragraph (f)(6)(ii)(B) to new § 422.100(f)(6)(ii)(C).
- Revising § 422.100(f)(6)(iii)(A) to refer to paragraph (f)(6)(iii) (instead of paragraph (f)(6)(ii)).
- Moving the rule identifying the Medicare data that CMS may utilize to calculate copayment limits subject to paragraph (f)(6)(iii) from proposed paragraph (f)(6)(iii)(B) to new § 422.100(f)(7)(i)(A).
- Finalizing new language at § 422.100(f)(6)(iii)(B) to: (1) clarify how CMS will apply the regulations to calculate copayments that are actuarially equivalent to the coinsurance limits, subject to other cited regulations; (2) refer to new paragraphs (f)(7) and (f)(8) to apply generally accepted actuarial principles and practices and restrictions on increases to the copayment limits to CMS's calculations of actuarially equivalent copayments; and (3) to provide if CMS does not calculate a copayment limit, the MA plan must not establish a copayment that exceeds the actuarially equivalent value to the coinsurance limits in paragraph (f)(6)(iii) based on the estimated total MA plan financial liability for that benefit for that contract year.
- Revising and adding new paragraphs at § 422.100(f)(6)(iii)(C) through (F) to adopt a transition over 4 years to the cost sharing limits for professional service categories based on use of the lower, intermediate, or mandatory MOOP type.
 - Revising § 422.100(f)(6)(iv)(A) to add a reference to new paragraph (f)(7).
- Revising § 422.100(f)(6)(iv)(B) to: (1) clarify the cost sharing limits calculated for the seven length of stay scenarios apply to inpatient hospital acute and psychiatric service categories; (2) remove the reference to an inpatient facility to match how CMS applies the inpatient hospital cost sharing limits; and (3) generally improve the flow of the regulation text.
- Revising § 422.100(f)(6)(iv)(C) to: (1) update the description of the Medicare FFS data used to calculate the inpatient hospital service category cost sharing limits for the applicable year

and length of stay scenario to reflect the ESRD cost transition; and (2) update the reference to the ESRD cost transition schedule to paragraphs (f)(4)(vii)(A) through (B) to reflect the modified transition finalized in section II.A. of this FC.

- Revising § 422.100(f)(6)(iv)(D) to: (1) clarify that this paragraph is applicable to inpatient hospital acute and psychiatric service categories; and (2) apply the rule proposed in paragraph (f)(6)(iv)(D)(3) that the total cost sharing for the inpatient benefit must not exceed the MA plan's MOOP limit or overall cost sharing for inpatient benefits in original Medicare on a per member per month actuarially equivalent basis (based on original Medicare cost sharing for a new benefit period) to all inpatient hospital cost sharing rather than only limited to MA plans that establish a lower MOOP amount.
- Revising § 422.100(f)(6)(iv)(D)(1) to clarify that the cost sharing for MA plans with a mandatory MOOP amount must not exceed 100 percent of estimated Medicare FFS cost sharing, including the projected Part A deductible and related Part B costs, for each length-of-stay scenario.
- Revising § 422.100(f)(6)(iv)(D)(2) to clarify that the cost sharing for MA plans with an intermediate MOOP amount must not exceed the cost sharing limits established in paragraphs (f)(6)(iv)(D)(1) and (3) for the same inpatient hospital length of stay scenario, before application of the rounding rules in paragraph (f)(6)(ii).
- Revising § 422.100(f)(6)(iv)(D)(3) to (1) clarify that CMS uses the projected Part A deductible to determine cost sharing limits for inpatient hospital acute and psychiatric services; (2) clarify that the flexibility to establish cost sharing above 125 percent of estimated Medicare FFS cost sharing is limited to the inpatient hospital acute 60 day length of stay for MA plans that establish a lower MOOP limit; (3) use consistent language when referring to inpatient hospital cost sharing; and (4) avoid repeating the rule moved to paragraph (f)(6)(iv)(D).
- Also, as discussed in section II.A. of this FC, adding § 422.100(f)(7)(i) to clarify that generally accepted actuarial principles and practices must be applied in the process of developing

the projections and calculations described in §§ 422.100(f)(4), (f)(5), (f)(6), (f)(7)(ii), (f)(8) and (i) and in 422.101(d)(2) and (3).

- Adding § 422.100(f)(7)(i)(A) to clarify in applying generally accepted actuarial principles and practices, actuarial judgment and discretion may be used, including to take into account relevant information, select among different approaches, and select data or data samples used in the calculations.
- Adding § 422.100(f)(7)(i)(B) to require MA organizations to also use generally accepted actuarial principles and practices in complying with the regulations in paragraphs (f)(6) and (j).
- Adding § 422.100(f)(7)(i)(C) to clarify that CMS will apply generally accepted
 actuarial principles and practices in evaluating MA organization compliance with § 422.100(f)(6)
 and (j).
- Adding § 422.100(f)(7)(ii) to adopt standards for whether and how CMS will calculate actuarially equivalent copayment limits for basic benefits subject to § 422.100(f)(6)(i), (f)(6)(iii), and (j)(1).
- Adding § 422.100(f)(7)(ii)(A) to provide that CMS will use Medicare FFS data projections (defined in paragraph (f)(4)(i)) to calculate an actuarially equivalent copayment value for the applicable year and service category.
- Adding § 422.100(f)(7)(ii)(B) to describe how CMS may use MA encounter data in addition to the Medicare FFS cost data projections.
- Adding § 422.100(f)(7)(ii)(C) to clarify how CMS may select among particular approaches to calculate actuarially equivalent copayment values in order to carry out program purposes.
- Adding § 422.100(f)(7)(ii)(D) to provide for applying the actuarially equivalent copayment transition in paragraph (f)(8) for calculating copayment limits.

- Adding § 422.100(f)(7)(ii)(E) to clarify use of the rounding rules in paragraph (f)(6)(ii) when calculating copayment limits at an actuarially equivalent value to the applicable cost sharing standard.
- Finalizing § 422.100(f)(7)(iii) to: (1) clarify that CMS will issue subregulatory guidance (beginning with contract year 2024) that specifies the MOOP limits and cost sharing standards for the upcoming contract year that are set and calculated using the methodology and standards in §§ 422.100(f) and (j), 422.101(d), and 422.113; (2) codify that this subregulatory guidance will be released prior to bid submission to allow sufficient time for MA organizations to prepare and submit plan bids; and (3) provide for a public notice and comment period on the projected MOOP limits and cost sharing standards for the upcoming contract year unless a public comment period is impracticable, unnecessary, or contrary to the public interest.
- Adding § 422.100(f)(8) to adopt a definition of and methodology for using an actuarially equivalent copayment differential (defined in paragraph (f)(8)(i)) to cap increases to copayment limits (for service categories subject to paragraph (f)(6)(iii) or (j)(1)) during the transition to actuarially equivalent copayment limits that ends in 2026, as described in detail in section II.B.5.b. and e. of this FC.
- Adding § 422.100(f)(9) to require MA organizations to bundle cost sharing amounts where separate cost sharing applies for that particular service(s) and setting(s) and be clearly reflected as a single, total cost sharing in appropriate materials distributed to beneficiaries for basic benefits.
- Redesignating the text at § 422.100(j)(1) to paragraph (j)(1)(i) and redesignating with modifications current paragraphs (j)(1), (j)(2) and (j)(3) as (j)(1)(i)(A), (j)(1)(i)(B), and (j)(1)(i)(C).
- Reorganizing the regulation text in paragraph (j)(1) and clarifying the description of the benefit in paragraph (j)(1)(i)(A) (proposed in $\S 422.100(j)(1)(i)$).

- Revising § 422.100(j)(1)(i) to: (1) clarify the scope of the requirement that cost sharing for certain services must not exceed cost sharing under original Medicare; and (2) require MA plans establishing a copayment for a service category subject to paragraph (j)(1)(i) to establish an amount that is equal to or less than an actuarially equivalent value to cost sharing required under original Medicare using the rules in paragraph (j)(1)(ii).
- Moving the regulatory text in proposed § 422.100(j)(1)(iii) to paragraph (j)(1)(i)(C) with the addition of specific per day cost sharing limits for the first 20 days of a SNF stay for each MOOP type.
- Moving the regulatory text in proposed § 422.100(j)(1)(iii)(A) and (B) to paragraphs (j)(1)(i)(C)(1) and (2) with a clarification that the per-day cost sharing for days 21 through 100 in a SNF must not be greater than one eighth of the projected (or actual) Part A deductible amount and a clarification that total cost sharing for the overall SNF benefit is also evaluated based on the per member per month actuarial equivalent value.
- Moving the regulatory text in proposed § 422.100(j)(1)(iv) to paragraph (j)(1)(i)(D) with modifications to change the requirement from cost sharing up to 20 percent of the total MA plan financial liability to cost sharing not greater than 20 percent or an actuarially equivalent copayment (the data which would make this determination is now contained in paragraph (j)(1)(ii)).
- Moving the regulatory text in proposed § 422.100(j)(1)(v) to paragraph (j)(1)(i)(E) with the following clarifications and additions: (1) the specific service categories applicable to paragraph (j)(1)(i)(E) for MA plans that establish a mandatory MOOP limit are: equipment, prosthetics, medical supplies, diabetes monitoring supplies, diabetic shoes or inserts; and (2) the requirement that the total cost sharing for the overall DME benefit must be no greater than the per member per month actuarially equivalent cost sharing for the DME benefit in original Medicare is applicable for all MOOP limits.

- Adding § 422.100(j)(1)(i)(F) to apply the requirement that cost sharing must not exceed cost sharing under original Medicare to the other drugs covered under Part B of original Medicare (that is, Part B drugs not included in paragraph (j)(1)(i)(A)).
- Adding § 422.100(j)(1)(ii) to codify the rules for calculating copayment limits for the basic benefits listed in paragraph (j)(1)(i) which include: (1) how CMS calculates copayment limits following the requirements in paragraph (f)(7) and the restrictions on changes in copayment amounts in paragraph (f)(8); and (2) how an MA plan must establish a copayment that does not exceed an actuarially equivalent value to the coinsurance required under original Medicare when CMS does not calculate a copayment limit for a benefit listed in paragraph (j)(1)(i) using actuarially accepted principles and practices included in paragraph (f)(7)(i) and basing calculations of an actuarially equivalent value on the average Medicare FFS allowed amount in the plan's service area or the estimated total MA plan financial liability for that benefit for that contract year.
- Revising § 422.100(j)(2) to clarify that this paragraph addresses the evaluation of all basic benefits and specific categories of basic benefits in the aggregate for which an MA plan's total cost sharing for all basic benefits (excluding out of network benefits covered by a regional MA plan) must not exceed cost sharing in original Medicare on a per member per month actuarially equivalent basis.
 - Revising § 422.100(j)(2)(i) to generally simplify and clarify regulation text.
- Revising § 422.100(j)(2)(i)(A) to: (1) clarify that services provided are during a covered inpatient stay; and (2) remove the language referencing an inpatient facility.
- Revising § 422.100(j)(2)(i)(C) to apply the requirement under paragraph (j)(2) to all drugs and biologics covered under Part B of original Medicare.
- Revising § 422.100(j)(2)(ii) to: (1) clarify that CMS extends the proposed flexibility to the evaluation of compliance with the requirements in paragraph (j)(2)(i) regarding actuarial equivalent cost sharing for all basic benefits and specific categories of basic benefits; and (2)

clarify that the flexibility is based on whether the MA plan's cost sharing for specific service categories otherwise satisfies applicable cost sharing standards and is based on "generally accepted actuarial principles and practices" (consistent with paragraph (f)(7)).

- Removing references to post-stabilization services costs in § 422.113(b)(2)(v).
- Revising § 422.113(b)(2)(v)(B)(1) to adopt the following emergency services cost sharing limits for 2023: \$95 for a mandatory MOOP limit, \$110 for an intermediate MOOP limit, and \$125 for a lower MOOP limit.
- Revising § 422.113(b)(2)(v)(B)(2) to adopt the following emergency services cost sharing limits for 2024: \$100 for a mandatory MOOP limit, \$120 for an intermediate MOOP limit, and \$135 for a lower MOOP limit.
- Revising § 422.113(b)(2)(v)(B)(3) to adopt the following emergency services cost sharing limits for 2025: \$110 for a mandatory MOOP limit, \$125 for an intermediate MOOP limit, and \$140 for a lower MOOP limit.
- Adding § 422.113(b)(2)(v)(B)(4) to adopt the following emergency services cost sharing limits for 2026 and subsequent years: \$115 for a mandatory MOOP limit, \$130 for an intermediate MOOP limit, and \$150 for a lower MOOP limit.
- Adding various minor technical and grammatical changes from the proposed regulation text at §§ 422.100(f)(6) and 422.113(b)(2) to ensure clarity and avoid repetitive text in the regulations.

Finally, in addition to the authority outlined in the February 2020 proposed rule for these cost sharing limits, section 1854(a)(5) and (6) of the Act provides that CMS is not obligated to accept every bid submitted and may negotiate with MA organizations regarding the bid, including benefits. Under section 1854(a)(5)(C)(ii) of the Act, CMS is authorized to deny a plan bid if the bid proposes too significant increases in enrollee costs or decrease in benefits from one plan year to the next. While the rules adopted here do not limit our negotiation authority (§ 422.256), they provide minimum standards for an acceptable benefit design for CMS to apply in

reviewing and evaluating bids in addition to establishing important protections to ensure that enrollees with high health care costs are not discouraged from enrolling in MA plans.

III. Request for Comment Regarding the Methodology for CMS to Update and Change Service Category Cost Sharing Limits (§ 422.100(f)(6)(i), (iii), and 422.100(j)(1))

We are requesting comments and information on new or different ways to update and change cost sharing limits for all service categories subject to §§ 422.100(f)(6)(i), (iii), and 422.100(j)(1), including mental health services, to inform future rulemaking. In brief, we are soliciting comments on: (1) modifying the cost sharing limits for specific service categories to better protect against potentially discriminatory cost sharing; and (2) the necessity, appropriateness and feasibility of adding parameters to update copayment limits after the cost sharing limit transitions are completed (based on § 422.100(f)(8)).

For the most part MA organizations typically offer benefits with lower cost sharing amounts than the cost sharing limits CMS has used in the past. However, we are concerned about benefit designs that have in-network cost sharing at the highest allowable level for a subset of benefits, including mental health services, even if the MA plans uses lower cost sharing for other benefits or categories of services. As a result, we are soliciting recommendations regarding the service categories for which CMS should consider modifying cost sharing limits (including specific cost sharing limits changes) to ensure beneficiaries are protected from potentially discriminatory cost sharing. For example, these recommendations could include adding new service categories, such as "mental health services" or categories that address substance use disorders, such as opioid treatment program services, to existing service categories at § 422.100(j)(1). The goal of these modifications would be to prohibit cost sharing amounts for those service categories that exceed cost sharing in original Medicare. By comparison, coinsurance limits for the "mental health services" service category in contract year 2022 were 50 percent regardless of the MOOP type established, and under this FC, by contract year 2026, the limit for the mental health services category will be, at the lowest, at the 30 percent

coinsurance limit (or actuarially equivalent copayment limit) for MA plans that establish a mandatory MOOP amount.

As established in this FC, CMS will annually update cost sharing limits based on more recent data and will use a 4-year transition period to move from the cost sharing limits set for contract year 2022 to a new set of coinsurance limits and actuarially equivalent copayment limits. For 2026 and subsequent years, this FC does not contain specific restrictions on increases in copayment limits and requires them to increase as the dollar value of the coinsurance percentage increases. We are soliciting comments on the necessity, appropriateness, and feasibility of preventing copayment limits from changing dramatically or fluctuating from year to year.

Our goal is to allow MA organizations to design stable benefit structures from year to year and meet beneficiary needs while ensuring that cost sharing is not discriminatory or excessive. We expect that having cost sharing standards that are predictable and stable from year to year supports this goal. A process that allows standards to change dramatically or fluctuate by minimal amounts from year to year would not promote stable benefit packages over time. In addition, we believe copayment limits should closely reflect the coinsurance amounts that MA enrollees are expected to pay and that copayment limits should be calculated using the applicable coinsurance percentages and considering and applying sound actuarial methods to reach an approximate actuarially equivalent value. We are soliciting ideas for regulatory, subregulatory, policy, practice, and procedural changes to better accomplish these goals. Ideas could include recommendations of specific actuarial approaches or parameters to do the following:

• Establish rules for when CMS should maintain or moderate the change from the prior year's copayment limits when calculating copayment limits for the upcoming contract year, while keeping copayment limits approximately in line with the coinsurance limits established in § 422.100(f)(6) and (j).

- Apply specific minimum and maximum thresholds to the methodology CMS uses to update copayment limits (with or without exceptions, such as for exceptional circumstances) in accordance with the regulations adopted in this FC.
- Ensure the methodology can be applied effectively to both service categories with higher and lower copayment limits.

CMS's overall goal in soliciting comments is to consider recommendations for how we can best mitigate disruption from changing copayment limits to ensure copayment limits do not become substantially different than the actuarially equivalent value to the coinsurance standard under this FC, while also striking a balance between protecting beneficiaries (especially vulnerable populations with higher-cost health care conditions) from excessive cost sharing and the costs experienced by MA organizations in providing the benefits. Commenters may also include recommendations regarding how CMS can simplify the rules and policies adopted here through future rulemaking to ensure beneficiaries have access to MA plans that meet the goals and objectives outlined in this FC as the basis for finalizing § 422.100(f)(6), (f)(7), (f)(8), and (j). Specific recommendations for how CMS can best evaluate MA compliance with the cost sharing standards adopted in this FC may also be provided in response to this solicitation. Comments regarding other cost sharing standards that CMS should consider for potential future rulemaking may also be submitted.

In responding to this comment solicitation, we request that all respondents provide complete, clear, and concise comments that include, where practicable, data and specific examples of how we may maintain or calculate updated copayment limits for these benefits in future years. If the proposals involve novel legal questions, analysis regarding our authority is welcome for our consideration. Language illustrating the suggested approach is also welcome so that CMS may understand more precisely the parameters of the suggestions. We are soliciting comment on all of the considerations discussed in this section.

This FC contains a request for comment. In accordance with the implementing regulations of the Paperwork Reduction Act of 1995 (PRA), specifically 5 CFR 1320.3(h)(4), this general solicitation is exempt from the PRA. Facts or opinions submitted in response to general solicitations of comments from the public, published in the **Federal Register** or other publications, regardless of the form or format thereof, provided that no person is required to supply specific information pertaining to the commenter, other than that necessary for self-identification, as a condition of the agency's full consideration, are not generally considered information collections and therefore not subject to the PRA.

We note that this request for comment is issued solely for information and planning purposes; it does not constitute a Request for Proposal (RFP), application, proposal abstract, or quotation. This request for comment does not commit the U.S. Government to contract for any supplies or services or make a grant award. Further, we are not seeking proposals through this request for comment and will not accept unsolicited proposals. Respondents are advised that the U.S. Government will not pay for any information or administrative costs incurred in response to this request for comment; all costs associated with responding to this request for comment will be solely at the interested party's expense. We note that not responding to this request for comment does not preclude participation in any future procurement or rulemaking, if conducted. It is the responsibility of the potential respondents to monitor this request for comment announcement for additional information pertaining to this request. In addition, we note that we will not respond to questions about the policy issues raised in this request for comment.

We will actively consider all input as we develop future plans and policies. We may or may not choose to contact individual respondents. Such communications would be for the sole purpose of clarifying statements in the respondents' written responses. Contractor support personnel may be used to review responses to this request for comment. Responses to this notice are not offers and cannot be accepted by the Government to form a binding contract or issue a grant. Information obtained as a result of this request for comment may be used by the

Government for program planning on a non-attribution basis. Respondents should not include any information that might be considered proprietary or confidential. This request for comment should not be construed as a commitment or authorization to incur cost for which reimbursement would be required or sought. All submissions become U.S. Government property and will not be returned. In addition, we may publicly post the public comments received, or a summary of those public comments.

IV. Collection of Information Requirements

The February 2020 proposed rule solicited public comment on our proposed information collection requirements (ICRs), burden, and assumptions for 17 provisions. We also solicited public comment on the provisions without ICRs and stated that those provisions did not propose any new or revised collection of information requirements and/or burden and, therefore, are not subject to the requirements of the Paperwork Reduction Act (PRA). We received no disagreement from the public commenters on this approach for the two provisions being implemented in this FC: (1) Maximum Out-of-Pocket (MOOP) Limits for Medicare Parts A and B Services (§§ 422.100 and 422.101); and (2) Service Category Cost Sharing Limits for Medicare Parts A and B Services and Per Member Per Month Actuarial Equivalence Cost Sharing (§§ 422.100 and 422.113).

In this FC we make some modifications to the proposals, including the addition of a transition period to implement the range of cost sharing limits for professional service categories (as discussed in section II.B.5.b. of this FC) and adjusting the percentage of ESRD costs to incorporate into the MOOP and inpatient hospital cost sharing limits for 2023 (as discussed in sections II.A.4.c. and II.B.5.c. of this FC), however these changes do not impose new or revised information collection requirements for these two provisions.

Consequently, we are finalizing that the two provisions do not impose any new or revised collection of information requirements and/or burden. In making this assertion we note that the finalized provisions codify and update current guidance governing MA organization bid

requirements⁶³, which are currently approved by OMB under control number 0938-0763 (CMS-R-262). This FC codifies general subregulatory guidance that we issued in past years about how benefits must be provided by MA plans (including MOOP and cost sharing guidance); because CMS annually reviews all bids, we are certain that there has been plan compliance with our current practice.

This FC also updates certain longstanding requirements and modifies the way that MOOP limits and cost sharing limits have been set by adopting specific methodologies but does not change how CMS evaluates compliance with MOOP and cost sharing limits as part of bid review. However, MA organizations are already submitting supporting documentation (for contract year 2022 and prior years) in order to demonstrate compliance. Similarly, CMS intends to continue providing annual instructions on bid documentation through subregulatory guidance.

Additionally, we received no PRA-related public comments for the provisions implemented in this FC.

Consequently, since there is no additional burden over and above the annual bid-review guidance and plan responses, we are finalizing our estimate of no impact without creating or modifying active ICR(s).

We note that the two MOOP and cost sharing provisions mentioned in this section are the only proposed provisions that are being finalized in this FC. The remaining proposed provisions from the February 2020 proposed rule were finalized in the June 2020 and January 2021 final rules.

V. Regulatory Impact Analysis

A. Statement of Need

The provisions in this FC codify and update current subregulatory guidance governing MA organization bid requirements. This includes changes to MOOP limits and inpatient hospital

⁶³ The CMS-R-262 PRA package may be accessed at: https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS-R-262.

cost sharing limits consistent with section 17006 of the 21st Century Cures Act (Cures Act), which amended section 1851(a)(3) of the Act to allow Medicare eligible beneficiaries with diagnoses of ESRD to choose an MA plan for Medicare coverage starting January 1, 2021, without the limits on such enrollment that currently apply. Prior to contract year 2021, we excluded the projected out-of-pocket spending for beneficiaries with diagnoses of ESRD, which we are also referring to in this FC as "ESRD costs," from the data used to set MOOP and cost sharing limits. After publication of the February 2020 proposed rule, we announced that we would incorporate a portion of ESRD costs into the data used to set and calculate MOOP and inpatient hospital cost sharing limits for contract year 2021⁶⁴. In addition, we maintained these MOOP and cost sharing limits for contract year 2022.65,66 This FC sets a specific schedule to incorporate the remaining ESRD costs into the MOOP and cost sharing limits. MOOP and inpatient hospital cost sharing limits will be calculated using the most recent Medicare FFS data based on the population with access to the MA program in order to be consistent with CMS's historical approach of uniformly spreading the burden of medical costs across all potential MA enrollees. This spreading of costs across all enrollees serves to ensure access to affordable and sustainable benefit packages for all eligible beneficiaries and is also consistent with how benefits must be covered uniformly with uniform cost sharing and premiums by MA plans.

This FC introduces a third MOOP limit as well as changes to cost sharing requirements, including how cost sharing limits will be set for professional services and updating the limits for emergency services. As noted in the February 2020 proposed rule, the percentage of eligible Medicare beneficiaries with access to an MA plan (excluding employer group waiver plans that limit enrollment to employer group members and D-SNPs) offering a voluntary MOOP amount

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⁶⁴ See the HPMS memorandum titled "Final Contract Year 2021 Part C Benefits Review and Evaluation," issued April 8, 2020, for information on MOOP and cost sharing limits for contract year 2021.

⁶⁵ See the HPMS memorandum titled "Final Contract Year 2022 Part C Benefits Review and Evaluation," issued May 20, 2021, for information on MOOP and cost sharing limits for contract year 2022.

⁶⁶ These HPMS memoranda may be accessed through the HHS guidance repository at: HHS Guidance Submissions | Guidance Portal and individuals and organizations may request placement on the HPMS listserv at https://hpms.cms.gov/app/ng/home/.

and the proportion of total enrollees in a voluntary MOOP plan have decreased considerably from contract year 2011 to contract year 2019. Based on plan data from March 2021, this trend has continued through contract year 2021 with approximately 18.5 percent of plans (21.5 percent of enrollees) having an in-network MOOP amount within the range of the prior voluntary MOOP limit (at or below \$3,400), as shown in Table 1. This percentage access increases to 23.3 percent of plans (24.8 percent of enrollees) for contract year 2021 after taking into consideration the increase to the lower MOOP limit for that year (at or below \$3,450). Consequently, we expect this trend to continue without intervention. A factor that may further spur this trend is that beneficiaries with diagnoses of ESRD are increasingly enrolling in the MA program because of their typical high health care costs, which the MA organization is financially responsible for after the ESRD enrollee reaches the MOOP amount. To abate this trend and incentivize MA organizations to offer lower MOOP amounts and/or lower or comparable cost sharing, this FC makes cost sharing limits for various service categories dependent on three distinct MOOP types. This FC reduces the cost sharing limits for professional services over a transition period from 50 percent to either 40 percent or 30 percent coinsurance (and actuarially equivalent copayments) for MA plans that use an intermediate or mandatory MOOP type and is a substantive change from longstanding practice. In proposing these changes, CMS also included a methodology to make updates to the cost sharing limits (for example, annually updating the copayment limits for professional services to actuarially equivalent values to align with the coinsurance standard based on the most recent Medicare FFS data projections) and a requirement for MA organizations to comply with cost sharing requirements in a particular manner (for example, using the MA plan total financial liability for a benefit to determine a copayment amount that reflects the coinsurance limit in cases where CMS has not calculated an actuarially equivalent copayment limit).

This rule also codifies the longstanding policy by CMS to calculate MOOP and cost sharing limits for specific service categories by calculating limits based on the most recent

Medicare FFS data projections. More specifically, CMS is codifying: (1) that CMS will use Medicare FFS data projections that, with modifications from past practice, incorporate data on the out of pocket costs of beneficiaries with diagnoses of ESRD over a specific schedule; (2) the percentiles used to calculate MOOP limits; (3) the 50 percent cost sharing limit for basic benefits covered by MA plans (which are Part A and B benefits excluding hospice and the costs of kidney acquisition for transplants); (4) the methodology CMS uses to calculate inpatient hospital acute and psychiatric cost sharing limits; (5) applying the cost sharing under original Medicare as a cost sharing limit to several service categories in MA; and (6) codifying that an MA plan's cost sharing for categories of basic benefits in the aggregate must not exceed cost sharing for those benefits in original Medicare on a per member per month actuarially equivalent basis. In codifying the general policies and approaches used in the past, CMS is also adopting some specific changes from its longstanding policy, including provisions regarding how updates to the MOOP and cost sharing limits are made each year and adopting the range of cost sharing flexibilities tied to using three MOOP limits. This FC, including the requirement to base MOOP and cost sharing limits on the most recent Medicare FFS data projections, is a significant improvement over the approach used in prior years, which did not have a specific methodology to recalibrate limits.

In response to comments on the February 2020 proposed rule, the timing of this FC, updated Medicare FFS data projections, and the potential impact of the COVID-19 pandemic since the February 2020 proposed rule, we are also finalizing several changes from the proposals, to smooth the transition to the new MOOP and cost sharing limit regulations. The major vehicle for smoothing this change is the use of multiyear transitions. With these multiyear transitions, we aim to avoid potentially disruptive cost sharing changes, such as sudden and substantive changes in cost sharing from the prior contract year and copayment limits that fluctuate up and down over short periods of time, for enrollees and plan designs.

These new multiyear transitions are used in the following provisions that are finalized in this rule: (1) the coinsurance and copayment limits for professional service categories; (2) the cost sharing limits for emergency services; and (3) and copayment limits for service categories for which cost sharing must not exceed cost sharing under original Medicare. This rule also finalizes (with modifications) the proposed multiyear transition for ESRD costs for MOOP limits and inpatient hospital cost sharing limits.

In the past, CMS set MOOP limits by striking a balance between limiting beneficiary outof-pocket costs and potential impact to plan design and costs and set cost sharing limits for specific benefits at amounts that CMS believed exceeding would be discriminatory for beneficiaries with high health needs. MA plans were required to have MOOP amounts and cost sharing at or below these limits set by CMS. This FC finalizes regulations with more specific rules for how the limits will be set to achieve the same and other similar program goals. We expect the finalized methodology to update cost sharing limits will be an improvement from prior years. Some of the contract year 2022 copayment limit amounts for professional service categories and benefits for which cost sharing must not exceed cost sharing under original Medicare have been in place for a number of years. Our proposed methodology to calculate copayment limits at actuarially equivalent values to the coinsurance standards being adopted in this rule is, in effect, a recalibration of these copayment limits by using a methodology adjusted from longstanding policy and the most recent Medicare FFS data projections available. Similarly, our proposed methodology to update copayment limits for emergency services considered updated Medicare FFS cost projections that MA organizations are expected to incur in providing these benefits. We expect that updating these copayment limits over several years to reflect the updated Medicare FFS data projections will be a significant improvement in how professional cost sharing standards are applied to MA plans compared to prior years. For example, these updates will incorporate costs resulting from medical inflation and new treatments that became available after the current copayment limits were originally set. Without

an actuarially acceptable and structured process to update copayment limits, the standards applied to MA plans could quickly become outdated and discourage MA organizations from establishing copayments over coinsurance structures in their plan designs. As noted in the February 2020 proposed rule, this would not be an ideal outcome as enrollees generally find copayment amounts more predictable and less confusing than coinsurance. CMS expects that this methodology will ultimately result in stable benefit packages by ensuring cost sharing limits are calculated following established actuarial methods, using the most recent Medicare FFS data projections available, and by keeping copayment limits aligned with coinsurance limits.

The regulatory impact statements for the provisions implemented in this FC are included in this section under the appropriate headings.

B. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866 defines a "significant regulatory action" as an action that is likely to result in: (1) having an annual effect on the economy of \$100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as "economically significant"); (2) creating a serious inconsistency or otherwise interfering with an action taken or

planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis must be prepared for major rules with significant regulatory action/s and/or with economically significant effects (\$100 million or more in any 1 year). This rule is economically significant under Executive Order 12866. The Office of Information and Regulatory Affairs has designated this rule as a major rule pursuant to the Congressional Review Act, 5 U.S.C. 804(2).

Section 202 of UMRA requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2022, that threshold is approximately \$165 million. This FC is not anticipated to have an unfunded effect on state, local, or tribal governments, in the aggregate, or on the private sector of \$158 million or more.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has federalism implications. Since this FC does not impose any substantial costs on state or local governments, preempt state law or have federalism implications, the requirements of Executive Order 13132 are not applicable.

If regulations impose administrative costs on reviewers, such as the time needed to read and interpret this FC, then we should estimate the cost associated with regulatory review. As of April 2021, there are 700 MA contracting organizations with CMS (which includes MA and MA-PD plans).⁶⁷ We also expect a variety of other organizations, such as advocacy groups, to review these regulations as well as MA organizations. We expect that each organization will

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⁶⁷ This information is publicly available and updated at the following website: https://www.cms.gov/research-statistics-data-and-systemsstatistics-trends-and-reportsmcradvpartdenroldatamonthly/contract-summary-2021-04

designate two people to review the rule. A reasonable maximal number is 2,000 total reviewers. We note that other assumptions are possible.

Using the BLS wage information for medical and health service managers (code 11–9111), we estimate that the cost of reviewing this FC is \$114.24 per hour, allowing 100 percent increase for fringe benefits and overhead costs (http://www.bls.gov/oes/current/oes_nat.htm). Assuming an average reading speed, we estimate that it will take approximately 8 hours for each person to review this entire FC. For each entity that reviews this FC, the estimated cost is therefore \$900 (8 hours x \$114.24). Therefore, we estimate that the maximum total cost of reviewing this entire FC is \$1.8 million (\$900 x 2,000 reviewers).

We note that this analysis assumed two readers per contract. Some alternatives include assuming one reader per parent organization. Using parent organizations instead of contracts will reduce the number of reviewers. However, we expect it is more reasonable to estimate review time based on the number of contracting MA organizations because a parent organization might have local reviewers assessing potential region-specific effects from this FC.

In accordance with the provisions of Executive Order 12866, this FC was reviewed by OMB.

C. Impact on Small Businesses – Regulatory Flexibility Analysis (RFA)

Executive Order 13272 requires that HHS thoroughly review rules to assess and take appropriate account of their potential impact on small business, small governmental jurisdictions, and small organizations (as mandated by the RFA). If a rule may have a significant economic impact on a substantial number of small entities, then that rule must discuss steps taken, including alternatives, to minimize burden on small entities. The RFA does not define the terms "significant economic impact" or "substantial number." The Small Business Administration (SBA) advises that this absence of statutory specificity allows what is "significant" or "substantial" to vary, depending on the problem that is to be addressed in the rulemaking, the rule's requirements, and the preliminary assessment of the rule's impact. Nevertheless, HHS

typically considers a "significant" impact to be 3 to 5 percent or more of the affected entities' costs or revenues.

For purposes of the RFA, we estimate that many affected payers are small entities as that term is used in the RFA, either by being nonprofit organizations or by meeting the SBA definition of a small business. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. The North American Industry Classification System (NAICS) is used to classify businesses by industry and is used by the United States, Canada, and Mexico. While there is no distinction between small and large businesses among the NAICS categories, the SBA develops size standards for each NAICS category. Note that the most recent update to the NAICS classifications went into effect for the 2017 reference year. The latest size standards are for 2019. The policies being implemented in this FC are: (1) Maximum Out-of-Pocket (MOOP) Limits for Medicare Parts A and B Services (§§ 422.100 and 422.101), and (2) Service Category Cost Sharing Limits for Medicare Parts A and B Services and Per Member Per Month Actuarial Equivalence Cost Sharing (§§ 422.100 and 422.113). These policies codify, modify, and update current guidance governing MA organization bid requirements.

This rule has several affected stakeholders. They include: (1) MA organizations offering MA plans such as HMOs, local and regional PPOs, MSAs, and PFFS plans; (2) providers, including institutional providers, outpatient providers, clinical laboratories, and pharmacies; and (3) enrollees. Note that cost plans are specifically excluded from the provisions of this rule and that the rule only affects Part A and B benefits (not Part D benefits) covered by MA plans. Some descriptive data on these stakeholders are as follows:

- Pharmacies and Drug Stores, NAICS 446110, have a \$30 million threshold for "small size" with 88 percent of pharmacies, those with under 20 employees, considered small.
- Direct Health and Medical Insurance Carriers, NAICS 524114, have a \$41.5 million threshold for "small size," with 75 percent of insurers having under 500 employees meeting the

definition of small business. Several Medicare Advantage plans (about 30-40 percent) are notfor-profit resulting in a "small entity" status.

- Ambulatory Health Care Services, NAICS 621, including about 2 dozen subspecialties, including Physician Offices, Dentists, Optometrists, Dialysis Centers, Medical Laboratories, Diagnostic Imaging Centers, have a threshold ranging from \$8 to \$35 million (Dialysis Centers, NAICD 621492, have a \$41.5 million threshold). Almost all firms are big, and this also applies to sub-specialties. For example, for Physician Offices, NAICS 621111, receipts for offices with under 9 employees exceed \$34 million.
- Hospitals, NAICS 622, including General Medical and Surgical Hospitals, Psychiatric and Substance Abuse Hospitals, Specialty Hospitals have a \$41.5 million threshold for small size, with half of the hospitals (those with between 20-500 employees) considered small.
- Skilled Nursing Facilities (SNFs), NAICS 623110, have a \$30 million threshold for small size, with half of the SNFs (those with under 100 employees) considered small.

The costs to MA organizations to cover Part A and B benefits for their enrollees are funded by the Federal government through the bidding process and the resulting capitated payments. Therefore, there is no significant burden on MA organizations to fund these benefits. We discuss the details of this immediately below in this section. This discussion will establish that there is no significant burden to a significant number of entities from this proposed rule for these provisions. Each year, MA plans submit a bid for furnishing Medicare Part A and B benefits (excluding hospice and the costs of acquisition of kidneys for transplant) as provided in section 1852 of the Act. The entire bid amount is paid by the government to the plan if the plan's bid is below an administratively set benchmark. If the plan's bid exceeds that benchmark, the beneficiary enrolled in the plan pays the difference in the form of a basic premium (note that a small percentage of plans bid above the benchmark and the enrollees in those MA plans must also pay an MA basic premium to the MA plan in addition to their Medicare Part B premium;

however, this percentage of plans is not "significant" as defined by the RFA and as justified below).

Under 42 CFR 422.100(c)(2) and 422.102, MA plans can also offer supplemental benefits that are not covered under Medicare Parts A, B and D. These supplemental benefits are paid for through enrollee premiums, extra government payments, or a combination of these.

Under the statutory payment formula, if the bid submitted by a MA plan for furnishing covered Part A and B benefits is lower than the administratively set benchmark, the government pays a portion of the difference to the plan in the form of a beneficiary rebate. The beneficiary rebate must be used by the MA plan to provide supplemental benefits and or/lower beneficiary Part B or Part D premiums. Some examples of these supplemental benefits include vision, dental, and hearing, fitness and worldwide coverage of emergency and urgently needed services.

To the extent that the government's total payments to plans, for the bid, risk adjustment, and the rebate, exceeds costs in Original Medicare, those additional payments put upward pressure on the Part B premium which is paid by all Medicare beneficiaries, including those in Original Medicare who do not have the enhanced coverage available in many MA plans.

Part D plans, including MA-PD plans, submit bids and those amounts are paid to plans through a combination Medicare funds and beneficiary premiums. In addition, for enrolled low-income beneficiaries Part D plans receive special government payments to cover most of premium and cost sharing amounts those beneficiaries would otherwise pay.

Thus, the cost of providing services by MA and Part D plans is funded by a variety of government funding and in some cases by enrollee premiums. As a result, MA and Part D plans are not expected to incur burden or losses since the private companies' costs are being supported by the government and enrolled beneficiaries. This lack of expected burden applies to both large and small health plans.

Small entities that must comply with MA regulations, such as those in this FC, are expected to include the costs of compliance in their bids, thus avoiding additional burden, since

the cost of complying with any final rule is funded by payments from the government and, if applicable, enrollee premiums.

For Direct Health and Medical Insurance Carriers, NAICS 524114, plans estimate their costs for the upcoming year and submit bids and proposed plan benefit packages. Upon approval, the plan commits to providing the proposed benefits, and CMS commits to paying the plan either--(1) the full amount of the bid, if the bid is below the benchmark, which is a ceiling on bid payments annually calculated from original Medicare data; or (2) the benchmark, if the bid amount is greater than the benchmark.

Thus, there is a cost to plans bidding above the benchmark that is not funded by government payments. Additionally, if an MA plan bids above the benchmark, section 1854 of the Act requires the MA plan to charge enrollees a premium for that amount. Table 29 reports the percent of the plans bidding above the benchmark along with the percent of affected enrollees in recent years. The table reports aggregates of proprietary bid data collected by the Office of the Actuary. The CMS threshold for what constitutes a substantial number of small entities for purposes of the RFA is 3 to 5 percent. As shown in Table 29, both the percentage of plans and the percentage of affected enrollees is decreasing and below this 3-5 percent threshold. Consequently, we may conclude that the number of plans bidding above the benchmark is not considered substantial for purposes of the RFA.

TABLE 29: PERCENTAGE OF PLANS BIDDING ABOVE BENCHMARK BY YEAR

Year	Number of Unique Bid IDs	Projected Enrollment (Member Months)	Number of Unique Bid IDs	Projected Enrollment (Member Months)	Bid ID Percentage	Enrollment Percentage
2020	100	2,108,026	4,270	231,754,722	2.3%	0.9%
2021	66	1,167,779	4,837	259,609,169	1.4%	0.4%
2022	30	328,621	5,298	288,151,395	0.6%	0.1%

The preceding analysis shows that meeting the direct cost of this FC does not have a significant economic impact on a substantial number of small entities, as required by the RFA.

Additionally, this FC is not expected to have impacts because: (1) several of its provisions are codifications of long-standing practices which CMS knows plans have complied with because of annual bid reviews; and (2) section 1852(a)(1)(B) of the Act requires MA plans to cover Part A and B benefits with cost sharing that is, in the aggregate, actuarially equivalent to cost sharing in the Original Medicare program.

There are certain indirect consequences of these provisions which also create impact. We have already explained that at least 98 percent of the plans bid below the benchmark. Thus, their estimated costs for the coming year are fully paid by the Federal government. However, the government additionally pays the plan a "beneficiary rebate" amount that is an amount equal to a percentage (between 50 and 70 percent depending on a plan's quality rating) multiplied by the amount by which the benchmark exceeds the bid. The rebate is used to provide additional benefits to enrollees in the form of reduced cost-sharing or other supplemental benefits, or to lower the Part B or Part D premiums for enrollees. (Supplemental benefits may also partially be paid by enrollee premiums.) However, as previously noted, the number of plans bidding above the benchmark to whom this burden applies do not meet the RFA criteria of a significant number of plans.

It is possible that if the provisions of this FC would otherwise cause bids to increase, plans will reduce their profit margins, rather than substantially change their benefit package. This may be in part due to market forces; a plan lowering supplemental benefits even for 1 year may lose its enrollees to competing plans that offer these supplemental benefits. Thus, it can be advantageous to the plan to temporarily reduce profit margins, rather than reduce supplemental benefits.

We next examine in detail each of the other stakeholders and explain how they can bear cost. Each of the following are providers (inpatient, outpatient, or pharmacy) that furnish plan-covered services to plan enrollees for: (1) Pharmacies and Drug Stores, NAICS 446110; (2) Ambulatory Health Care Services, NAICS 621, including about two dozen sub-specialties,

including Physician Offices, Dentists, Optometrists, Dialysis Centers, Medical Laboratories, Diagnostic Imaging Centers, and Dialysis Centers, NAICD 621492; (3) Hospitals, NAICS 622, including General Medical and Surgical Hospitals, Psychiatric and Substance Abuse Hospitals, and Specialty Hospitals; and (4) SNFs, NAICS 623110. Whether these providers are contracted or, in the case of PPOs and PFFS, not contracted with the MA plan, their aggregate payment for services is the sum of the enrollee cost sharing and plan payments. For non-contracted providers, § 422.214 and sections 1852(k)(1) and 1866(a)(1)(O) of the Act require that a non-contracted provider accept payment that is at least what they would have been paid had the services been furnished in a fee-for-service setting. For contracted providers, § 422.520 requires that the payment is governed by a mutually agreed upon contract between the provider and the plan. CMS is prohibited from requiring MA plans to contract with a particular healthcare provider or to use a particular price structure for payment under the plan by section 1854(a)(6)(B)(iii) of the Act. Consequently, for these providers, there is no additional cost burden above the already existing burden in original Medicare.

Based on the above considerations, the Secretary has certified that this FC will not have a significant impact on a substantial number of small entities.

In addition, Section 1102(b) of the Social Security Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. With regard to the section 1102(b) requirements for hospitals, while this rule does have a provision relating to inpatient hospital cost sharing limits, this rule imposes a burden neither on rural or non-rural hospitals because this FC applies only to enrollee cost sharing and does not require any changes in the amounts paid to hospitals. For example, after the MOOP amount is reached, hospitals are

paid in full (by the plan or secondary insurance) with the enrollee paying nothing out of pocket.

Consequently, the Secretary has certified that this FC does not impost a burden on hospitals.

D. Executive Order 13132 (Federalism)

Executive Order 13132, "Federalism," establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct requirement costs on State and local governments, preempts state law, or otherwise has Federalism implications. The Department has determined that this FC will not impose such costs or have any Federalism implications.

E. Consultation and Coordination with Indian Tribal Governments

We have analyzed this FC in accordance with the principles set forth in Executive Order 13175. We have determined that this FC does not contain policies that would have a substantial direct effect on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes.

F. National Environmental Policy Act (NEPA)

We have determined that this FC will not have a significant impact on the environment.

G. Anticipated Effects of Maximum Out-of-Pocket (MOOP) Limits for Medicare Parts A and B

Services (§§ 422.100 and 422.101) and Service Category Cost Sharing Limits for Medicare Parts

A and B Services and Per Member Per Month Actuarial Equivalence Cost Sharing (§§ 422.100 and 422.113

This FC is identified as economically significant which corresponds to the observation that certain groups of beneficiaries may have significant savings or losses. Nevertheless, for three reasons, we expect no aggregate impact to enrollees from the MOOP limit and Cost Sharing provisions adopted in this FC. First, there is a statutory requirement for submitted bids to be actuarially equivalent to coverage in original Medicare, implying that plans can shift costs, but not create additional out of pocket costs for enrollees compared to the original Medicare

program. Even if there are shifts in enrollee out of pocket costs, in aggregate there will be no dollar impact. This is operationalized through an actuarial equivalence test that is a projection that MA cost sharing under each MA plan equals Medicare FFS cost sharing. At the time that the actuarially equivalent cost sharing amounts are calculated, the expectation is that there will be no costs or savings for the policy year in question.

Second, many provisions in this FC are codifications of long-standing policies. CMS is confident that this codification will not result in dollar impact, because CMS annually reviews bids, and has observed compliance with the bid requirements.

Third, an analysis of plan bid changes from contract year 2020 to 2021 provides supportive quantitative evidence that plans, for marketing reasons and because of the principles and incentives inherent in managed care, are not (in most cases) establishing the highest allowable MOOP amount. We note the \$6,700 in-network mandatory MOOP limit calculated for contract year 2020 has been longstanding and we used this as a baseline to determine if MOOP amounts were being substantially increased under the new, higher MOOP limits. For example, based on March 2021 MA and MA-PD plan data, after CMS increased MOOP limits for contract year 2021 (using Medicare FFS data with 40 percent of ESRD costs), approximately 63 percent of plans established a MOOP amount below \$6,700 (compared to approximately 65 percent with a MOOP amount below \$6,700 for contract year 2020). This example highlights how MA organizations typically offer benefits with lower enrollee cost sharing responsibility than the annual limits published by CMS.

MOOP and cost sharing limits are important beneficiary protections and integral to ensuring that MA enrollees who need extensive or expensive health care services because of their health status do not face discrimination. While the overall statutory requirement that cost sharing in an MA plan must be at least actuarially equivalent to cost sharing in original Medicare limits the overall costs that MA plans must cover in their bids and overall out-of-pocket costs for enrollees, the ability to change or set cost sharing for different benefits at different levels could

potentially be used by MA plans to discourage enrollment by beneficiaries with high health needs or specific types of health needs (for example, specific specialist services). Requiring MOOP and cost sharing limits in MA plan design in addition to the statutorily required MOOP limits for regional MA plans is necessary in order not to discourage enrollment by individuals who utilize higher than average levels of health care services (that is, in order for a plan not to be discriminatory in violation of section 1852(b)(1) of the Act). Such considerations have been the basis for CMS to set specific MOOP limits and cost sharing limits under existing regulations over the past several years. We proposed adopting transparent rules to govern how those MOOP and cost sharing limits for local and regional plans are set each year, including rules for incorporating out-of-pocket costs incurred by beneficiaries with diagnoses of ESRD ("ESRD costs" in this discussion) into the methodology for calculating MOOP limits and cost sharing standards, to provide stability for MA organizations and plan enrollees. Prior to this FC, we calculate MOOP and cost sharing limits annually and this process will continue as codified.

In preparing plan bids for contract year 2023 and future years to which this FC is applicable, we expect MA organizations may, as a result of the provisions of this FC, make adjustments to their benefit design, for example, increasing the MOOP amount and/or specific service category cost sharing. However, as indicated at the beginning of this section, which presents three arguments, we do not expect these changes will have a significant aggregate impact.

A substantive change of this FC from the February 2020 proposed rule is inclusion of multiyear transitions to adjust cost sharing limits for: (1) professional service categories; (2) emergency services; and (3) benefits for which cost sharing must not exceed cost sharing under original Medicare. For example, we finalized a multiyear transition from the 50 percent professional cost sharing limit to a range of cost sharing limits (30, 40, and 50 percent) based on the MOOP type. We expect that a multiyear implementation schedule will be helpful to: (1) mitigate potentially disruptive changes based on the projected increases to certain service

category copayment limits resulting from using the Medicare FFS data projections; and (2) be responsive to commenter requests to provide time for MA organizations and enrollees to adjust to updated cost sharing limits.

We also proposed a multiyear transition schedule of incorporating costs related to Medicare-eligible enrollees with diagnoses of ESRD into the methodology we use to calculate MOOP and inpatient hospital acute and psychiatric cost sharing limits. We proposed to complete this transition by factoring in the ESRD costs into the methodology through an ESRD cost differential (which was generally finalized as proposed as a specific way to measure ESRD costs and factor them into the data used for calculating the MOOP and cost sharing limits). We proposed to transition the ESRD cost differential for both MOOP and inpatient hospital acute and psychiatric cost sharing limits as follows: 60 percent in 2022; 80 percent in 2023; and 100 percent in 2024. As discussed in sections II.A. and B. of this FC, we are finalizing the multiyear transition of ESRD costs into MOOP and cost sharing limits to complete in contract year 2024 as proposed, but given the delay in releasing a final rule for these provisions we are adjusting the ESRD cost differential percentage for contract year 2023 from 80 to 70 percent. The MOOP and cost sharing limits were maintained for contract year 2022 in the absence of a final rule for these provisions; we did not incorporate 60 percent of the ESRD cost differential in contract year 2022 as proposed. We expect judiciously adjusting the percent of ESRD cost differential in contract year 2023, while maintaining the final date by which the multivear transition is completed (2024), will mitigate the risk of potential increased premiums or decreased benefits that may be associated with the migration of ESRD beneficiaries from Medicare FFS to the MA program and minimize disruption to beneficiaries. Under the finalized methodology, the ESRD cost differential is incorporated as follows: for 2023, 70 percent and for 2024, 100 percent. As discussed in the February 2020 proposed rule, we recognize incorporating ESRD costs would increase all in-network and combined MOOP limits for local and regional MA plan types, but including ESRD costs is an important and necessary step to ensure that plan designs are not

discriminatory and protect beneficiaries from high and unreasonable financial costs regardless of the MA plan. We coordinated the MOOP and cost sharing proposals in sections VI.A. and B. of the February 2020 proposed rule in an effort to prevent substantial increases in MOOP limits, cost sharing limits, and premiums to protect beneficiaries, and proposed reasonable updates and flexibilities for MA organizations to offer sustainable MA plans with stable benefit designs.

As discussed in the February 2020 proposed rule, CMS expects transitioning ESRD costs into the data used to calculate MOOP and cost sharing limits may result in a combination of savings and costs for MA organizations. Depending upon an individual's health status and health care coverage selections, some enrollees may experience increased costs while others may experience decreased costs. CMS is not able to quantify these potential impacts precisely.

Accordingly, we provide background and a qualitative discussion to share our rationale. The cost to the MA organization of having a MOOP amount and reduced cost sharing is captured as a supplemental benefit in the bid pricing tool if the MA organization's decision about how to establish MOOP and cost sharing amounts for its plan design results in overall aggregate cost sharing for Medicare-covered benefits for that MA plan to be less than actuarially equivalent to cost sharing in original Medicare. With a higher MOOP limit or cost sharing (as a result of incorporating ESRD costs and/or using the most recent Medicare FFS data to calculate copayment limits), the cost of the MOOP limit and benefits are lower to the MA organization which allows additional rebate dollars to be spent elsewhere (for example, for cost sharing reductions or additional benefits). From an actuarial perspective, on average, the MA enrollee is receiving the same level of benefits in total (of course, individual impacts will vary). MA organizations can continue to structure their PBP to be actuarially equivalent to FFS (without supplemental benefits) through the cost sharing flexibilities that this FC includes. As a result, we expect the MOOP and Cost Sharing provisions will have no material aggregate impact.

Enrollment impacts from section 17006 of the 21st Century Cures Act are addressed in sections III.A., VII.B.3., and VIII.D.1. of the June 2020 final rule (85 FR 33796). Before the

amendments made by the 21st Century Cures Act were effective for contract year 2021, individuals diagnosed with ESRD could not enroll in an MA plan, subject to limited exceptions. Generally, those exceptions included the following circumstances: an individual that developed ESRD while enrolled in an MA plan could remain in that plan; an ESRD individual enrolled in a plan which terminated or discontinued had a one-time opportunity to join another plan; or, an individual could enroll in a special needs plan that had obtained a waiver to be open for enrollment to individuals with ESRD. CMS calculated separate payment rates to address the higher costs MA plans may experience when managing care for enrollees with ESRD, and has been continuing to do so after Medicare beneficiaries with diagnoses of ESRD were allowed to enroll in MA plans in greater numbers.

MA organizations have been aware of the program change to allow Medicare beneficiaries with diagnoses of ESRD to enroll in MA since section 17006 of the Cures Act was enacted in December 2016. Accordingly, CMS expects MA organizations have planned and prepared for this program change by conducting business activities, such as evaluating plan benefits, provider contracting with network providers, developing case management programs, and addressing reinsurance arrangements as applicable. Following the 21st Century Cures Act, the OACT projected the number of individuals with diagnoses of ESRD that may enroll in MA.68 In the February 2020 proposed rule we referenced this projection; OACT expected ESRD enrollment in MA plans to increase by 83,000 as a result of the Cures Act provision69. The OACT assumed the increase would be phased in over 6 years, with half of those beneficiaries (41,500) enrolling during 2021. Based on actual 2021 enrollment data, the OACT continues to

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⁶⁸ The Fiscal Year President's Budgets may be accessed at https://www.govinfo.gov/app/collection/BUDGET/ and the annual Advance Notice and Rate Announcements may be accessed at https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents.

⁶⁹ The estimated cost per year to the Medicare Trust Fund based on this enrollment projection of beneficiaries with diagnoses of ESRD is available in Table 7 on page 33887 in section VIII.D.1. of the June 2020 final rule (85 FR 33796) https://www.federalregister.gov/documents/2020/06/02/2020-11342/medicare-program-contract-year-2021-policy-and-technical-changes-to-the-medicare-advantage-program .

project that 83,000 beneficiaries with diagnoses of ESRD will enroll in the MA program over 6 years.

CMS notes that MA organizations are in a competitive market and design their plan bids to manage risk, encourage enrollment, and satisfy Medicare coverage requirements. CMS does not require MA organizations to disclose these strategies, and as such, cannot quantitatively project what savings or costs MA organizations may incur from the changes in MOOP and cost sharing limits. CMS's goal is to provide predictable and transparent MOOP limits and cost sharing standards and to calculate limits at a level that should not result in significant new costs for MA organizations or enrollees. By taking the program changes from section 17006 of the 21st Century Cures Act into account within our existing process to calculate and update MOOP limits and cost sharing standards, we are protecting MA enrollees against high out-of-pocket costs and sudden changes in those costs.

As discussed in the February 2020 proposed rule, CMS believes the MOOP limit in the MA program provides a protection to MA enrollees from high out-of-pocket costs. CMS notes beneficiaries with diagnoses of ESRD previously enrolled in Medicare FFS with or without Medigap coverage may experience different cost sharing and out-of-pocket costs if they switch to an MA plan. For example, a Medicare beneficiary with a diagnosis of ESRD enrolled in Medicare FFS (without Medigap or employer coverage) may experience higher out-of-pocket costs annually if their annual health care treatment out-of-pocket costs go above the MOOP limit required for MA plans.

CMS cannot precisely project the individual cost impacts for enrollees and MA organizations in its proposed MOOP and cost sharing limit changes because potential savings and costs are largely influenced by--

• The rate of transition for Medicare beneficiaries with diagnoses of ESRD into the MA program;

- Enrollee cost sharing information including how many individuals (with and without ESRD) reach the MOOP, variability in reaching the MOOP by year, and frequency of utilization of services both below the MOOP and above the MOOP; and
- The mechanisms MA organizations choose to address this programmatic change, such as provider contracting, case management, plan benefit designs, and benefit flexibilities including Special Supplemental Benefits for the Chronically Ill, MA uniformity flexibility, and the proposed MOOP limits and cost sharing flexibilities, while additionally making sure the plan bid remains actuarially equivalent to original Medicare.

By implementing more than two levels of MOOP limits and providing increased flexibility in calculating cost sharing amounts for MA organizations with lower MOOP limits, we expect to encourage plan offerings with favorable benefit designs for Medicare beneficiaries to choose from. We note that beneficiaries consider the MOOP limit and cost sharing structure when choosing an MA plan, however we do not expect them to face more complex plan options due to our regulatory changes. From a beneficiary's perspective, the individual will have the ability to review the same volume of information about MOOP limits and cost sharing structures as currently available. We also do not expect MA organizations to necessarily offer more plan options than they currently do as a result of this change. MA organizations can already create different MOOP amount and cost sharing structures based on a number of market factors that may, or may not, be related to beneficiaries with ESRD diagnoses being able to enroll in MA plans. Additionally, CMS will continue evaluations and enforcement of its current authority prohibiting plans from misleading beneficiaries in their marketing and communication materials and continue efforts to improve plan offerings and plan comparison tools and resources (for example, Medicare & You and 1-800-MEDICARE). Consistent with statutory requirements, CMS will not approve a plan bid if its proposed benefit design substantially discourages enrollment in that plan for certain Medicare-eligible individuals.

We did not receive any comments that specifically referenced the cost impact of the MOOP and cost sharing proposals.

H. Alternatives Considered

In this section, CMS includes discussions of Alternatives Considered to implement the provisions to which they are applicable. We note a more detailed discussion of the finalized implementation approach and the mechanics of operationalizing it for the policies discussed in this section is available in sections II.A. and B. of this FC. When considering the alternative transition scenarios presented in this section, the actuarial equivalence tests are still upheld, implying that in aggregate the expected enrollee cost sharing expenses will remain the same for those enrollees in MA and for those enrollees in FFS. Consequently, there are no expected changes to the Medicare Trust Fund expenditures since aggregate enrollee cost sharing remains unchanged under the alternative scenario(s). Additionally, several provisions of this FC codify long-standing existing polices used by CMS in annual bid reviews, implying that no additional dollar impact across the program as a whole will occur.

Throughout section V.H.1. and 2. of this FC we list alternatives, including multiyear transitions, for each or for combinations of the provisions. The multiyear transitions considered are generally consistent with the transition methodology proposed to incorporate ESRD costs into MOOP and inpatient hospital cost sharing limits. At a high level, all alternatives considered sought to strike a balance between: (1) finalizing policies that would incentivize MA organizations to establish lower MOOP amounts; and (2) protecting enrollees from potential disruption that may result from substantially shifting MOOP and copayment limits within 1 year.

Throughout this section, each alternative would result in a terminal year in which MOOP limits and cost sharing standards are at 100 percent of what we proposed, with one exception for the "Part B drugs – other" service category (as explained in detail in sections II.B.5.e. and V.H.2. of this FC). The main difference between the alternatives is the length of time in which the finalized provisions are not fully in effect. In the February 2020 proposed rule, CMS developed

the proposals to apply to contract year 2022 and future years. However, we did not finalize these provisions in advance of the contract year 2022 bid deadline. Consequently, we needed to delay implementation of the provisions in this FC to contract year 2023 and future years. This led us to use the MOOP limits and cost sharing standards that were set for contract year 2022 as the baseline (as shown in Tables 30, 31, and 33 through 37) for comparing the proposed and finalized policies. The level to which the provisions are in effect during the transitional period described in each alternative is described as a percentage in most cases. For example, 100 percent signifies that the transitional period has concluded and the provisions are fully implemented as finalized in this FC.

These transitions are examined through tables and narratives indicating consequences. While we project that there is no dollar impact to the Medicare Trust Fund from any of these alternatives, certain transitions may have unintended adverse beneficiary and marketing impacts. More specifically, a transition that is implemented too quickly may have an unintended effect of increasing cost sharing for certain services too quickly (based on the most recent Medicare FFS data projections available at the time of this FC). Such sudden increases would be expected to-

- Result in beneficiary concern;
- Potentially affect the "total beneficiary cost"; and
- Potentially steer certain sets of beneficiaries away from enrolling in the MA program or to different plans (this might have quantitative adverse impact, but we have no way of knowing how each group of beneficiaries would react nor how many are involved).

Similarly, a transition that is too slow is not useful or protective to enrollees. This delay would contradict the very purpose of using updated Medicare FFS data projections to calculate MOOP limits and cost sharing limits for inpatient services; this might result in MA organizations making other changes to their bid design, such as increasing premiums or reducing benefits. However, we have no way to quantify the potential adverse effects this may cause.

To avoid repetitive text, throughout this section we reference potential disruption generally instead of repeating the preceding paragraphs. Specifically, references to potential disruption include one or more of the adverse consequences listed previously in this section. Our goal in considering these alternatives in implementation is to achieve a balance in the transition, not too fast and not too slow for the stakeholders involved (namely, enrollees and MA organizations). Details of the projected MOOP and cost sharing limits that would result from the various alternatives (which motivated CMS in choosing a final implementation approach) are available in the tables and discussions in sections V.H.1. and 2. of this FC.

1. Maximum Out-of-Pocket (MOOP) Limits for Medicare Parts A and B Services (§§ 422.100 and 422.101)

CMS considered two alternatives to finalize the ESRD cost transition into the methodology CMS uses to calculate MOOP limits at specific percentiles of beneficiary out of pocket costs in the Medicare FFS program. We note this part of the MOOP provision makes substantive changes to existing policy. Specifically, we considered alternatives in the rate and length of the ESRD cost transition due to all the following:

- Timing of this FC.
- Potential for enrollee disruption and impacts of further delays in integrating ESRD costs.
- Public comments on the MOOP limit proposals (as summarized in section II.A.4. of this FC).

The transition schedule we proposed incorporated the ESRD cost differential as follows: 60 percent in 2022; 80 percent in 2023 or the next year; and 100 percent in 2024 or the final year of transition. In addition, our proposal included guardrails to pause the incorporation of the ESRD cost differential if the dollar figure at the 85th or 95th percentile of projected Medicare FFS costs increased or decreased too much (as defined in the February 2020 proposed rule as a difference of more than 2 percentiles above or below the 85th and 95th percentile) from the prior

year. We note other schedules to phase in ESRD costs are possible and we expect each unique transition would have different beneficiary and marketing impacts through its completion. Our goal, as indicated in the introduction of this section, is to minimize disruption.

The projections from the OACT in the February 2020 proposed rule on expected enrollment of 83,000 Medicare beneficiaries with diagnoses of ESRD into the MA program appear to align with actual enrollment based on 2021 enrollment data. As such, the delay of this FC resulted in the proposed 60 percent of the ESRD cost differential not being incorporated into contract year 2022 MOOP limits while enrollment of beneficiaries with diagnoses of ESRD in MA is projected to increase. Finally, as summarized in section II.A. of this FC, we received some public comments requesting changes to the proposed transition, including an accelerated transition of ESRD costs into the methodology CMS uses to calculate MOOP limits. As a result, CMS considered the following alternatives:

Alternative 1: We considered finalizing the ESRD transition as proposed for contract years 2023 and 2024 (that is, incorporating 80 percent of the ESRD cost differential for contract year 2023 and 100 percent for contract year 2024 if the dollar figure at the 85th or 95th percentile of projected Medicare FFS costs did not increase or decrease more than 2 percentiles above or below the 85th and 95th percentile from the prior year) to minimize the changes from the proposal to only address the delay of the final rule release. Table 30 illustrates the impact of this alternative on contract year 2023 in-network MOOP limits in comparison to the other alternatives and baseline limits described in this section. Table 31 demonstrates the same comparison for contract year 2023 total catastrophic (combined) MOOP limits.

As shown in Tables 30 and 31, finalizing 80 percent of the ESRD cost differential for contract year 2023 would increase the MOOP limits at a greater rate than illustrated in the February 2020 proposed rule (using updated projections based on Medicare FFS data from 2017 – 2021). For example, in the February 2020 proposed rule the highest allowable in-network mandatory MOOP limit for contract year 2023 was projected to be \$7,950 and this alternative

implemented with updated projections based on 2017 – 2021 Medicare FFS data increased this amount to \$8,700 (a \$750 increase) as shown in Table 30. We also note this would reflect a \$1,150 increase from the highest allowable in-network mandatory MOOP limit of \$7,550 in contract year 2022. The increases to the MOOP limits resulting from this alternative shown in Table 30 (and by extension based on how the total catastrophic MOOP limits are calculated, Table 31) also reflect implementing the proposed guardrails to pause the incorporation of the ESRD cost differential if the dollar figure at the 85th or 95th percentile of projected Medicare FFS costs increased or decreased too much (as defined in the February 2020 proposed rule). For example, the projected 95th percentile of projected Medicare FFS costs increased from \$8,468 to \$9,111 between contract year 2022 and 2023, in comparison the 97th percentile of projected Medicare FFS costs (for contract year 2022) was \$11,837. As the projected contract year 2023 95th and 85th percentiles did not increase or decrease more than 2 percentiles above or below the contract year 2022 95th and 85th percentiles, the cap of a 10 percent change from the prior year's MOOP limit was not applied (as proposed) in Tables 30 and 31.

We considered these higher projected increases in relation to actual contract year 2021 plan MOOP changes, potential impacts of further delays in integrating ESRD costs, and feedback from public commenters in determining the final ESRD cost transition as further described in this section. Ultimately, we expect that transitioning from 40 percent of the ESRD cost differential (initially incorporated for contract year 2021 and maintained for 2022) to 80 percent for contract year 2023 would have a greater potential to produce disruptive consequences (such as, greater disenrollment from the MA program as a result of potential plan benefit design changes) than reducing the percentage of ESRD costs that are incorporated for contract year 2023. As a result, we declined to adopt the ESRD cost transition exactly as proposed for contract year 2023 as we believe that another approach would better protect against potential enrollee disruption and be responsive to public commenters.

Alternative 2: Second, we considered extending the proposed ESRD cost transition schedule by 1 year (that is, incorporating 60 percent of the ESRD cost differential for contract year 2023, 80 percent for contract year 2024, and 100 percent for contract year 2025) and implementing the guardrails to pause the incorporation of the ESRD cost differential if the dollar figure at the 85th or 95th percentile of projected Medicare FFS costs increased or decreased too much (as defined in the February 2020 proposed rule) as generally proposed (applied to each year of the transition). We believe this is another approach to minimize the changes from the February 2020 proposed rule, provide MA organizations with adequate time to prepare for these changes, and to avoid potentially disruptive changes for enrollees. Table 30 provides the projected impact of finalizing this alternative on contract year 2023 in-network MOOP limits in comparison to the other alternatives and baseline limits described in this section. Table 31 demonstrates the same comparison for the total catastrophic MOOP limits.

As shown in Table 30, finalizing 60 percent of the ESRD cost differential for contract year 2023 would increase the highest allowable in-network mandatory MOOP limit to \$8,350, an increase of \$400 from the illustrative \$7,950 amount in the February 2020 proposed rule using contract year 2023 Medicare FFS data projections (based on 2017 – 2021 Medicare FFS data). This \$8,350 amount also reflects a \$800 increase from the highest allowable in-network mandatory MOOP limit of \$7,550 in contract year 2022. In comparison, the highest allowable in-network mandatory MOOP limit increased from \$6,700 to \$7,550 (\$850) from contract year 2020 to 2021 as a result of the Medicare FFS data percentile projections (based on 2015 – 2019 Medicare FFS data) and 40 percent of the ESRD cost differential being incorporated.

For the same reasons as discussed in the first alternative of this section, the increases to the MOOP limits resulting from this alternative do not reflect the application of a 10 percent change cap from the prior year's MOOP limit because the updated 95th and 85th percentiles did not increase or decrease more than 2 percentiles above or below the 95th and 85th percentiles from the prior year. Given this potential increase, we reviewed the changes MA plans made in

establishing their contract year 2021 MOOP amounts and determined that most MA organizations were not utilizing the full flexibility from the increased MOOP limits. Comparing contract year 2020 and 2021, we found that approximately 35 percent of all MA and MA-PD plans established the highest allowable MOOP amount (\$6,700) for contract year 2020 and approximately 37 percent of all MA and MA-PD plans chose to establish a MOOP amount at or above \$6,700 for contract year 2021. This indicates a modest increase in the percent of plans with the highest allowable MOOP amount from the prior contract year on an aggregate basis. This data does not suggest that incorporating a greater percentage of the ESRD cost differential is likely to result in most MA organizations substantially increasing their MOOP amounts for contract year 2023 (as they already could increase their MOOP amounts further and chose not to for contract year 2021). However, we acknowledge that our data are limited to comparing the change between contract year 2020 and 2021. As a result, we cannot make a definitive prediction on how MA organizations may utilize the available flexibility in establishing their plan MOOP amounts for future years.

Feedback from public commenters (as summarized and responded to in section II.A. of this FC) included requests for an accelerated transition of ESRD costs into the methodology CMS uses to calculate MOOP limits given the potential for faster growth of ESRD enrollment in the MA program and geographic variations. In addition, the delay of this FC resulted in no increased ESRD cost adjustments in calculating contract year 2022 MOOP limits while enrollment of beneficiaries with diagnoses of ESRD in MA is projected to increase. Extending the ESRD cost transition would effectively produce changes that are contrary to commenter feedback, are not consistent with the increased costs MA organizations may experience based on enrollment projections, and are not sufficiently supported by the number of plans using the existing level of flexibility in MOOP limits. As a result, we rejected this alternative ESRD cost transition schedule because the data and public commenter feedback summarized previously did

not suggest that an extended transition of ESRD costs in the methodology to calculate MOOP limits was justified or necessary to protect against potential enrollee disruption.

Alternative 3 (Finalized): We are finalizing most of our proposals to codify and update the methodology CMS uses to calculate MOOP limits, except we are modifying the multiyear transition of ESRD costs and not finalizing the provision that would delay (or toll) the incorporation of ESRD costs into the data used to calculate the MOOP limits. The finalized schedule judiciously modifies the transition of ESRD costs into the methodology to calculate MOOP limits by incorporating 70 percent of the ESRD cost differential for contract year 2023 (instead of the proposed 80 percent). In addition, we are finalizing the timing of the conclusion of the ESRD cost transition as proposed with 100 percent of the ESRD cost differential incorporated for contract year 2024. In addition, beginning for contract year 2023 we are finalizing a modified version of the proposed 10 percent change cap from the prior year's MOOP limit to prevent increases greater than 10 percent, without the additional requirements of meeting the two percentiles change threshold. In finalizing this ESRD cost transition schedule we are especially considerate of the potential impact of further delays in integrating ESRD costs, comments on the proposed transition schedule, and the possibility of enrollee disruption. Table 5 contains the final contract year 2023 MOOP limits and Table 9 contains illustrative contract year 2024 MOOP limits, which were developed using the methodology finalized in this FC. The calculations of the MOOP limits in Tables 5 and 9 using the methodology finalized in this FC and projections of 2017 - 2021 Medicare FFS data are in Tables 2 - 4 and 6 - 8.

The proportion of ESRD cost differential incorporated into the MOOP limits for contract year 2023 was finalized at 70 percent instead of 80 percent as proposed. The impact of incorporating 80 percent (with the requirement that to apply the 10 percent cap on changes to the MOOP limit the respective percentiles of Medicare FFS costs would need to exceed two percentiles from the prior contract year) using contract year 2023 Medicare FFS data projections (based on 2017 - 2021 Medicare FFS data) is addressed in our discussion of the first alternative

in this section and illustrated in Tables 29 and 30. In comparison, as shown in Table 30, this finalized approach increased the highest allowable in-network mandatory MOOP limit for contract year 2023 from the \$7,950 illustrative amount in the February 2020 proposed rule to \$8,300 (a \$350 increase) using projections of Medicare FFS costs based on 2017 – 2021 Medicare FFS data. The \$8,300 amount also reflects a \$750 increase from the highest allowable in-network mandatory MOOP limit of \$7,550 in contract year 2022. This increase to the mandatory MOOP limit was calculated using the contract year 2022 mandatory MOOP limit plus 10 percent of that amount and applying the rounding rules at § 422.100(f)(4)(iii) as the 10 percent cap on increases was met (without the requirement to exceed two percentiles from the prior contract year as described in section II.A.4. of this FC). The delay of this FC resulted in no increased ESRD cost adjustments in calculating contract year 2022 MOOP limits (versus the 20 percent increase proposed) while ESRD enrollment in MA is projected to increase in 2022. As a result, we considered changes to the ESRD cost transition to reduce the potential disruption from transitioning to 80 percent of the ESRD cost differential in 1 year (from 40 percent that was incorporated in contract year 2021 and maintained for contract year 2022). While the proportion of MA plans with mandatory MOOP amounts did not significantly change between contract year 2020 and 2021 (approximately 2 percent as discussed previously in this section) this trend may not continue if MOOP limits do not fully reflect ESRD costs as ESRD enrollment in the MA program continues to increase. For example, as indicated in our discussion of disruption in section V.H. of this FC, delaying the ESRD cost transition may result in MA organizations choosing to use the maximum level of flexibility that is available (increasing the MOOP amount to the maximum MOOP limit to a greater extent than prior years) or making other changes to their plan benefit designs (increasing premiums or cost sharing amounts) in order to compensate for the additional costs they would be covering.

In addition, feedback from public commenters (as summarized and responded to in section II.A. of this FC) included requests for an accelerated transition of ESRD costs into the

methodology CMS uses to calculate MOOP limits given the potential for faster growth of ESRD enrollment in the MA program and geographic variations. While the finalized approach does not accelerate the timeframe to fully integrate ESRD costs into MOOP limits, as some commenters requested, the transition schedule as finalized strikes a balance between curbing more significant increases to MOOP limits from contract year 2022 and helping ensure that MA organizations are able to continue offering all plan enrollees, regardless of their ESRD status, high-quality care and service while keeping premiums and out-of-pocket costs at non-discriminatory levels. By striking this balance and continuing our longstanding practice of calculating MOOP limits based on Medicare FFS data projections, CMS expects the finalized transition schedule will also mitigate the risk of increased premiums or decreased benefits that may be associated with the migration of beneficiaries with diagnoses of ESRD from Medicare FFS to the MA program.

As noted in section V.G. of this FC, because of multiple factors affecting bids and our longstanding actuarially equivalent plan bid requirements, we have not estimated a cost to this provision and acknowledged a possible combination of savings and costs for individual MA organizations and enrollees. Similarly, we would not be able to quantify potential impacts from these alternatives. However, potential impacts from the alternatives are noted previously in this section.

TABLE 30: ILLUSTRATIVE COMPARISON OF ALTERNATIVES AND FINALIZED MOOP LIMIT METHODOLOGY ON HIGHEST ALLOWABLE CONTRACT YEAR 2023 IN-NETWORK MOOP LIMITS BASED ON PROJECTIONS OF 2017 – 2021 MEDICARE FFS DATA

ESRD Cost Transition Methodology	Lower	Intermediate	Mandatory
Baseline: Contract Year 2022 Limits	\$3,450	N/A	\$7,550
Alternative 1: Incorporate 80% of the ESRD Cost Differential	\$3,700	\$6,200	\$8,700
Alternative 2: Incorporate 60% of the ESRD Cost Differential	\$3,600	\$5,950	\$8,350
Alternative 3 (Finalized): Incorporate 70% of the ESRD Cost Differential	\$3,650	\$6,000	\$8,300

TABLE 31: ILLUSTRATIVE COMPARISON OF ALTERNATIVES AND FINALIZED MOOP LIMIT METHODOLOGY ON HIGHEST ALLOWABLE CONTRACT YEAR 2023 (COMBINED) TOTAL CATASTROPHIC MOOP LIMITS BASED ON PROJECTIONS OF 2017 – 2021 MEDICARE FFS DATA

ESRD Cost Transition Methodology	Lower	Intermediate	Mandatory
Baseline: Contract Year 2022 Limits	\$5,150	N/A	\$11,300

Alternative 1: Incorporate 80% of the ESRD Cost Differential	\$5,550	\$9,300	\$13,100
Alternative 2: Incorporate 60% of the ESRD Cost Differential	\$5,400	\$8,950	\$12,500
Alternative 3 (Finalized): Incorporate 70% of the ESRD Cost Differential	\$5,450	\$8,950	\$12,450

2. Service Category Cost Sharing Limits for Medicare Parts A and B Services and Per Member Per Month Actuarial Equivalence Cost Sharing (§§ 422.100 and 422.113)

Similar to our approach for the MOOP limit provision, CMS developed several alternatives to finalizing the specific proposals on Cost Sharing that make substantive updates to existing policy. These proposals include the following:

- Range of Cost Sharing Limits for Certain Outpatient and Professional Services (§ 422.100(f)(6)(iii)).
- Emergency/Post-Stabilization Services and Urgently Needed Services (§ 422.113(b)(2)(v) and (vi)).
 - Services No Greater Than Original Medicare (§ 422.100(j)(1))

We considered alternatives due to all of the following:

- Timing of this FC.
- Potential for enrollee disruption.
- Public comments on the Cost Sharing proposals (as summarized in section II.B.5. of this FC).

After the February 2020 proposed rule was released, we received updated Medicare FFS projections for service category cost sharing amounts from the OACT that were not available at the time of drafting the February 2020 proposed rule (for example, updated average and median allowed amount Medicare FFS data projections based on 2017 through 2021 Medicare FFS data). We evaluated the potential enrollee disruption resulting from the use of these updated amounts to calculate actuarially equivalent copayment limits. Finally, as summarized in section II.B. of this FC, we received public comments requesting changes to our proposals, including applying a transition to the range of cost sharing limits for professional services and delays to increases to cost sharing for emergency services.

In this section we address the consequences of alternatives that were considered in response to the factors and feedback discussed previously. While each cost sharing proposal, such as the ones for emergency services or the ones for the copayment limits for professional services, had unique aspects, we present the narrative discussing the alternatives for all of these proposals in one section (as the approach is generally the same for each provision). However, the tables in this section show how each alternative would uniquely impact the copayment limits that are subject to a particular policy (either §§ 422.100(f)(6)(iii), (j)(1), or 422.113(b)(2)(v)).

The following tables contain the projected impact of finalizing each of the alternatives discussed in this section on contract year 2023 cost sharing limits for particular service categories:

- Table 33: Physical therapy and speech-language pathology.
- Table 34: Partial hospitalization.
- Table 35: Emergency services.
- Table 36: Part B drugs chemotherapy/radiation drugs.
- Table 37: Part B drugs other.

A more complete discussion of the data analyses completed to reach the actuarially equivalent values of the copayment limits in Tables 33 through 37 is available in the February 2020 proposed rule and section II.B.5 of this FC. In addition, the cost sharing limits in Tables 33 through 37 for Alternative 3 are final amounts resulting from CMS applying the regulations using contract year 2023 Medicare FFS data projections (based on 2017 – 2021 Medicare FFS data). In addition, the specific emergency services cost sharing limits in Table 35 for Alternative 3 in section V.H.2.c. of this FC are codified in § 422.113(b)(2)(v) for contract year 2023. We note that no additional Medicare FFS data projections were used to calculate the cost sharing limits for emergency services during the transition in Table 35 (all amounts were based on the specified dollars limits from the February 2020 proposed rule). A complete list of final contract

year 2023 in-network cost sharing limits calculated following the methodology in this FC is available in Table 28.

Alternative 1: We considered finalizing the three cost sharing proposals (in §§ 422.100(f)(6)(iii), (j)(1), and 422.113(b)(2)(v)) for use of the proposed coinsurance percentages and use of actuarially equivalent copayment limits to begin immediately for contract year 2023 as an approach to minimize the changes from the February 2020 proposed rule and to incentivize MA organizations to establish lower MOOP amounts. This alternative would result in the most substantial increases to the contract year 2023 cost sharing limits, as shown in Tables 33 through 37 in comparison to the other alternatives discussed in this section. We ultimately rejected this alternative to be responsive to public comments and apply another approach that would better protect enrollees from potential disruption that may result from substantially shifting copayment limits within 1 year.

As shown in Table 33, finalizing the range of cost sharing limits for contract year 2023 would increase the physical therapy and speech-language pathology copayment limit for a plan that establishes a lower MOOP amount to \$90, a \$5 increase from the illustrative amount in the February 2020 proposed rule (using contract year 2023 Medicare FFS data projections based on 2017 – 2021 Medicare FFS data). This \$90 amount also reflects a \$50 increase from the contract year 2022 copayment limit for this service category. Similarly, as shown in Table 34, this alternative would increase the partial hospitalization copayment limit for a plan that establishes a lower MOOP amount to \$135. This \$135 amount reflects a \$80 increase from the contract year 2022 copayment limit for this service category.

As shown in Table 35, finalizing the proposed emergency services cost sharing limits for contract year 2023 would increase the cost sharing limit for a plan that establishes a lower MOOP amount from \$120 in contract year 2022 to \$150 for contract year 2023 and future years (an increase of \$30) as generally illustrated in the February 2020 proposed rule. These specific

cost sharing limits would apply unless cost sharing established by the MA plan if the emergency services were provided through the MA organization is lower.

As shown in Table 36, the 20 percent coinsurance limit (cost sharing under original Medicare) for the Part B drugs – chemotherapy/radiation drugs service category remains consistent with the cost sharing standards CMS has used since 2012. In addition, using contract year 2023 Medicare FFS data projections (based on 2017 – 2021 Medicare FFS data) for the Part B drugs – chemotherapy/radiation drugs service category, an actuarially equivalent copayment value based on 20 percent coinsurance would be \$280. As a result, if this first alternative were finalized, beginning in contract year 2023 MA organizations could establish a \$280 copayment (a \$205 increase from the \$75 copayment limit for Part B drugs – chemotherapy/radiation drugs for contract year 2022) which would be potentially disruptive to enrollees.

As shown in Table 37, to be consistent with the February 2020 proposed rule for this alternative, we considered the alternative under which we would apply the range of cost sharing limits (30, 40, and 50 percent) for the "Part B drugs – other" service category rather than our longstanding 20 percent coinsurance requirement. This alternative would increase the cost sharing limit for a plan that establishes a lower MOOP amount from \$50 or 20 percent coinsurance in contract year 2022 to \$800, or 50 percent coinsurance for contract year 2023 (an increase of \$750). Specifically, \$800 reflects an actuarially equivalent value to 50 percent coinsurance for the "Part B drugs – other" service category using contract year 2023 Medicare FFS data projections (based on 2017 – 2021 Medicare FFS data).

We note that if we instead codified the 20 percent coinsurance limit without a transition, based on the same contract year 2023 Medicare FFS data projections, the actuarially equivalent copayment limit would be \$320 for the "Part B drugs – other" service category in contract year 2023. Based on these significant projected increases to the "Part B drugs – other" copayment limit in comparison to the contract year 2022 limit (as shown in Table 37), we decided to address this service category differently from the other service categories we proposed to be subject to

§ 422.100(f)(6)(iii) for the rest of this section. Specifically, instead of finalizing a range of cost sharing for this service category, we considered both codifying our longstanding 20 percent coinsurance requirement and applying a multiyear transition to an actuarially equivalent copayment value based on 20 percent coinsurance in the other alternatives discussed in this section.

In relation to the cost sharing limits in Tables 33, 34, 36, and 37, as discussed in section II.B.5. of this FC, if CMS does not calculate a copayment limit for a service category subject to § 422.100(f)(6)(iii) or (j)(1) (which would also be consistent with the February 2020 proposed rule), an MA plan must not establish a copayment that exceeds an actuarially equivalent value to the cost sharing standard. This means the potential outcomes shown in Tables 33, 34, 36, and 37 for this alternative remain essentially the same in the absence of a copayment limit calculated by CMS. For example, if CMS did not set a contract year 2023 partial hospitalization service category copayment limit for MA plans with a lower MOOP amount those plans may still be able to establish up to an \$135 copayment under this alternative for contract year 2023 (the same amount shown in Table 34 for this alternative).

As discussed in section II.B. of this FC, calculating copayment limits based on updated Medicare FFS data projections reflects plan costs associated with the variety and expense of services included in the cost sharing limit. In addition, calculating a maximum cost sharing limit of up to 50 percent coinsurance or an actuarially equivalent copayment value for a lower MOOP type is consistent with CMS's longstanding interpretation and application of the anti-discriminatory requirements, which is that cost sharing over 50 percent for services - where there are no other applicable cost sharing limits – is discriminatory to enrollees who need those services. However, our proposed methodology to calculate copayment limits based on specified percentages is, in effect, a recalibration of the copayment limits in one year by using a methodology adjusted from longstanding policy and updated Medicare FFS data projections. As a result, implementing this alternative means that some of the projected copayment limits in

Tables 33 through 37 represent substantial disruptive shifts from the prior contract year since enrollees could experience changes in copayments up to those amounts. As discussed in the introduction to section V.H. of this FC, we understand such increases (in conjunction with the other projected increases to MOOP limits as discussed in more detail in section II.A. and V.H.1. of this FC) could have significant disruptive consequences for enrollees, especially if they have limited financial means.

Public comments (as summarized and responded to in section II.B.5. of this FC) were mixed on these three cost sharing proposals (in §§ 422.100(f)(6)(iii), (j)(1), and 422.113(b)(2)(v)and (vi)). In brief, some commenters generally opposed the proposed increases to the cost sharing limits for certain service categories (such as physical therapy and speech-language pathology, emergency services, and dialysis services) as they stated it may prevent MA enrollees from having meaningful access to services and substantial changes to copayment limits from one year to the next should be avoided to reduce disruption in the market and for beneficiaries. Other commenters were supportive as they stated it would provide an incentive for MA organizations to offer plans with lower MOOP amounts. In addition, a commenter requested CMS conduct a multiyear transition from the current cost sharing limits to the range of cost sharing limits proposed given the potential for enrollee disruption (based on the projected changes to cost sharing limits in the February 2020 proposed rule). While we respond to these (and other) comments in section II.B.5. of this FC, we agree that it is important that enrollees do not face unexpected financial hardships in accessing needed health care services. Further, finalizing these proposals for contract year 2023, when the actuarially equivalent copayment limits for some professional service categories have increased to a greater extent than illustrated in the February 2020 proposed rule (using contract year 2023 Medicare FFS data projections based on 2017 – 2021 Medicare FFS data) would not have fully addressed the concerns raised in those public comments that CMS shared.

In summary, implementing this alternative to finalize as proposed (with the delay of implementation of the three cost sharing proposals from contract year 2022 to 2023) would mean that many of the copayment limits for services categories subject to §§ 422.100(f)(6)(iii), (j)(1), and 422.113(b)(2)(v) and (vi) would substantially increase from the prior contract year. Based on the enrollee's situation, these changes would be disruptive; they could, for example, potentially discourage them from seeking those services with increased cost sharing and/or result in enrollees choosing to disenroll from the plan or the MA program. We rejected this alternative because the data and public commenter feedback summarized previously did not suggest that implementing these proposals without a transition would sufficiently protect enrollees from potentially significant year over year changes.

Further, CMS has a practice of phasing in changes in the MA program in order to avoid unnecessary disruption and to ensure a smooth transition. For example, CMS began incorporating encounter data into risk score calculations in 2015 as an additional source of diagnoses. Between 2016 and 2022, CMS calculated risk scores for MA organizations using a weighted average of RAPS-based and encounter data-based risk scores, gradually phasing in encounter data in risk score calculation. In 2022, CMS completed the transition to calculating risk scores for payment to MA organizations using only encounter data. Similarly, the 21st Century Cures Act mandated that several changes be made to the Part C risk adjustment model for MA organizations, and that these changes be phased in over a 3-year period, beginning with 2019, with the changes being fully implemented for 2022. CMS began implementing the risk adjustment requirements in the Cures Act in 2019, with a portion of the risk score applied in payments to MA organizations calculated with a risk adjustment model that included new condition categories. CMS continued implementation by calculating an increasing portion of the risk score used for payments for 2020 and 2021 using a model that included additional condition categories and factors that take into account the total number of diseases or conditions of a beneficiary. For 2022 payment to MA organizations, the risk adjustment model that meets Cures Act requirements was fully phased in. This history has demonstrated the value of using transition schedules when incorporating changes into the MA program.

Alternative 2: We considered: (1) finalizing a 5-year transition to implement the three cost sharing proposals (with one exception for the "Part B drugs – other" service category) beginning for contract year 2023; (2) codifying our longstanding requirement of 20 percent coinsurance (the cost sharing under original Medicare) for the "Part B drugs – other" service category; (3) calculating copayment limits for the "Part B drugs – other" service category consistent with the 5-year transition (rather than immediately using a copayment limit that is actuarially equivalent to the coinsurance limit); and (4) requiring that CMS set copayment limits at an amount that is the lesser of: an actuarially equivalent value to the applicable cost sharing standard or the value resulting from the 5-year actuarially equivalent copayment transition for that service category. In considering these changes our goal is to protect against potential enrollee disruption, provide MA organizations with adequate time to prepare for these changes, and to incentivize MA organizations to establish lower MOOP amounts. This alternative would result in the least substantial increases to the contract year 2023 cost sharing limits as shown in Tables 33 through 37 in comparison to the other alternatives discussed in this section. However, we ultimately rejected this alternative because of potential disruptive consequences resulting from an extended transition as discussed at the beginning of this section and in section V.H. of this FC (for example, MA organizations increasing premiums or reducing benefits).

The detailed aspects of operationalizing a multiyear transition for these proposals is provided in section II.B.5 of this FC. Our goal in this Alternative Considered section is to analyze the individual cost sharing and difficult-to-quantify impacts of various alternatives. However, in order to understand the long-term implications of this alternative, we summarize the coinsurance limits that would be applied for service categories subject to § 422.100(f)(6)(iii) in Table 32. Table 32 is not included in section II.B. of this FC as that section focuses on the finalized methodology (the third alternative in this section). In addition, Table 32 is only relevant

to service categories subject to paragraph (f)(6)(iii) as the coinsurance limit for benefits subject to § 422.100(j)(1) would not need to be transitioned (20 percent coinsurance remains consistent with contract year 2022) and the cost sharing limits for emergency services in § 422.113(b)(2)(v) do not include coinsurance limits (before our proposal and as proposed). As shown in Table 32, CMS would maintain the 50 percent coinsurance limit for the lower (previously "voluntary") MOOP type and transition the contract year 2022 coinsurance limit of 50 percent for the mandatory MOOP type to the proposed 30 percent coinsurance limit by decreasing the limit 4 percent each year. In addition, as finalized in section II.A. of this FC, the intermediate MOOP limit is a new type of MOOP beginning in contract year 2023. In order to provide consistently differentiated coinsurance limits between the MOOP limits through the 5-year transition, we would set a 48 percent coinsurance limit for contract year 2023 for the intermediate MOOP limit and decrease it by 2 percent each year to reach the proposed 40 percent coinsurance by contract year 2027.

TABLE 32: ALTERNATIVE 2 – A 5-YEAR TRANSITION TO REACH THE RANGE OF COINSURANCE LIMITS BASED ON THE MOOP TYPE FOR SERVICE CATEGORIES SUBJECT TO § 422.100(f)(6)(iii)

MOOP Type	2023	2024	2025	2026	2027 and Future Years
Lower	50%	50%	50%	50%	50%
Intermediate	48%	46%	44%	42%	40%
Mandatory	46%	42%	38%	34%	30%

In implementing the requirement that CMS set copayment limits at an amount that is the lesser of: (1) an actuarially equivalent value to the applicable cost sharing standard; or (2) the value resulting from the 5-year actuarially equivalent copayment transition for that service category, we note the first value would be the actuarially equivalent copayment to the coinsurance limit shown in Table 32. The second value would result from CMS factoring in an increasing percentage of the difference (or differential) between two values: (1) the contract year 2022 copayment limit for the service category; and (2) the actuarially equivalent value for that service category based on the proposed cost sharing standards. (This is similar to the approach

we finalized in § 422.100(f)(8) but using a different schedule.) We note this definition is explained in greater detail in section II.B.5. of this FC (for instance, how CMS would apply it to the copayment limits applicable for MA plans that have an intermediate MOOP limit). Unique to this alternative, this differential would be factored in over 5 years for service categories subject to §§ 422.100(f)(6)(iii), (j)(1), and 422.113(b)(2)(v) by factoring in the differential as follows:

- Contract Year 2023: 20 percent
- Contract Year 2024: 40 percent
- Contract Year 2025: 60 percent
- Contract Year 2026: 80 percent
- Contract Year 2027: 100 percent

By factoring in 100 percent in contract year 2027 CMS would complete the transition to actuarially equivalent copayment values at the same time the range of coinsurance limits are completed in Table 32 (that is, the copayment limits calculated for contract year 2027 would be actuarially equivalent to the coinsurance limits that apply for that year as we proposed for contract year 2022).

As shown in Table 33, finalizing a 5-year transition to the range of cost sharing limits reduces the increase to the physical therapy and speech-language pathology copayment limit for a plan that establishes a lower MOOP amount compared to the first alternative discussed in this section (using Medicare FFS data projections based on 2017 -2021 Medicare FFS data). For example, the contract year 2023 copayment limit for the physical therapy and speech-language pathology service category if a plan establishes a lower MOOP amount would be \$50 under this alternative. This \$50 amount reflects a \$35 decrease compared to the \$85 illustrative copayment limit in the February 2020 proposed rule. In addition, this \$50 amount is a \$10 increase from the contract year 2022 copayment limit of \$40 for this service category (compared to a \$50 increase for the lower MOOP limit if the first alternative discussed in this section was implemented).

Similarly, as shown in Table 34, this alternative would result in a \$70 contract year 2023 copayment limit for the partial hospitalization service category for a plan that establishes a lower MOOP amount. This \$70 amount reflects a \$15 increase compared to the contract year 2022 copayment limit of \$55 for this service category. The copayment limits in Table 33 and 34 also reflect implementing the "lesser of" requirement (for both alternative two and three in this section); each copayment limit calculated from factoring in an increasing percentage of the actuarially equivalent copayment differential over the transition period was less than the amount that would be actuarially equivalent to the coinsurance limit that would apply in contract year 2023 (as listed in Table 32 and described in the third alternative in this section).

As shown in Table 35, applying a 5-year transition would reduce the impact of the increase to the emergency services cost sharing limit for a plan that establishes a lower MOOP amount from \$120 in contract year 2022 to \$125 for contract year 2023, an increase of \$5 from the prior contract year instead of the \$30 increase, as illustrated in the February 2020 proposed rule. As no coinsurance limits for emergency services were proposed, the requirement that CMS set copayment limits at an amount that is the lesser of: (1) an actuarially equivalent value to the applicable cost sharing standard; or (2) the value resulting from the actuarially equivalent copayment transition for that service category does not apply to emergency services.

Table 36 illustrates that applying a 5-year transition would reduce the increase to the Part B drugs – chemotherapy/radiation drugs service category copayment limit; the copayment limit would increase from \$75 in contract year 2022 to \$115 for contract year 2023. This \$115 amount reflects an increase of \$40 from the prior contract year and a decrease of \$165 in comparison to the first alternative in this section (using contract year 2023 Medicare FFS data projections based on 2017 – 2021 Medicare FFS data). The copayment limits in Table 36 also reflect implementing the "lesser of" requirement (for both alternative two and three in this section); each copayment limit calculated from factoring in an increasing percentage of the actuarially equivalent copayment differential over the transition period was less than the amount that would

be actuarially equivalent to the coinsurance limit that would apply in contract year 2023 (20 percent, reflecting the cost sharing in original Medicare).

Table 37 shows applying this alternative for the "Part B drugs – other" service category produces substantially lower copayment limits than the first alternative discussed in this section (using the same contract year 2023 Medicare FFS data projections). This is because the differential between the contract year 2022 limit and the final cost sharing limits that would be applied in contract year 2027 is reduced from a maximum of \$800 (for the lower MOOP limit under the first alternative) to \$105 (for all MOOP types under this alternative). Specifically, Table 37 applies a 5-year transition to reach an actuarially equivalent copayment limit to our longstanding 20 percent coinsurance requirement for the "Part B drugs – other" service category. For example, under this alternative the contract year 2023 "Part B drugs – other" service category copayment limit for a plan that establishes a lower MOOP amount would be \$105, an increase of \$55 from the \$50 contract year 2022 copayment limit. In comparison, the increase from contract year 2022 would be \$750 from the first alternative in this section (which would have used a 50 percent coinsurance limit for the lower MOOP type). Finally, the copayment limits shown in Table 37 for both the second and third alternative discussed in this section also reflect implementing the "lesser of" requirement; each copayment limit calculated from factoring in an increasing percentage of the actuarially equivalent copayment differential over the transition period was less than the amount that would be actuarially equivalent to the coinsurance limit that would apply in contract year 2023 (20 percent).

If CMS does not set a copayment limit for a service category subject to § 422.100(f)(6)(iii) or (j)(1) (which would also be consistent with the February 2020 proposed rule), an MA plan must not establish a copayment that exceeds an actuarially equivalent value based on the coinsurance limit. In comparison, the contract year 2023 copayment limits that would result from this alternative (and the third alternative in this section) in Tables 33, 34, 36, and 37 are not solely based on being actuarially equivalent to the coinsurance limit, using

contract year 2023 Medicare FFS data projections (based on 2017 – 2021 Medicare FFS data). Rather, they are influenced by the contract year 2022 copayment limits through the increasing incorporation of the differential (and the requirement to set the copayment limit using the lesser value) as discussed previously in this section. As a result, if CMS does not set a copayment limit during a multiyear transition period (following this alternative or the third alternative discussed in this section) for a service category subject to paragraph (f)(6)(iii) or (j)(1), the copayments MA organizations may establish for that service category may be higher or lower than the values in Tables 33, 34, 36, and 37. The potential administration burden for each service category for which CMS does not calculate a copayment limit would remain the same as discussed previously in this section. Further information about how MA organizations may approach preparing supporting documentation for their cost sharing amounts is available in section II.B.5.a. of this FC.

As discussed in section II.B. of this FC, the copayment limits set for some service categories (subject to § 422.100(f)(6)(iii) and (j)(1) in this FC) in past years do not reflect current actuarially equivalent values using contract year 2023 Medicare FFS data projections (based on 2017 – 2021 Medicare FFS data). In applying a multiyear transition to recalibrate copayment limits and a requirement to set copayment limits at the lower value, enrollees will be better protected from potential disruption and MA organizations will have more time to consider different cost sharing structures and approaches, such as using copayment structures (which may be more transparent for beneficiaries) instead of coinsurance, or using lower cost sharing than the maximum permitted.

However, as indicated in the introduction to this Alternative Section, applying a lengthy multiyear transition to reach the proposed range of cost sharing limits may not provide an incentive for MA organizations to adopt a lower MOOP amount as quickly. In addition, an earlier completion of the transition will: (1) improve the alignment of copayment limits with the coinsurance limits; (2) increase the flexibility MA organizations have in establishing

copayments; (3) may encourage the use of copayments and lower MOOP amounts among MA plans; and (4) mitigate potential premium increases or benefit reductions. Further, MA organizations were able to, and may continue to, establish cost sharing equal to original Medicare for all benefits subject to paragraph (j)(1) and cost sharing up to 50 percent coinsurance for professional service categories subject to § 422.100(f)(6)(iii) in contract year 2022 and prior years through coinsurance structures. Some MA organizations may have chosen to use coinsurance structures in their benefit designs because of geographic variation in health care costs. While CMS is finalizing the policies in this FC in a manner to avoid potentially disruptive changes for enrollees wherever possible, a longer transition schedule for service categories subject to paragraph (j)(1) means that the copayment limits remain out of proportion to the consistent 20 percent coinsurance limit for a longer period of time. If CMS maintained copayment limits at lower than actuarial equivalent amounts for a long period of time, MA organizations may still modify their plan benefit designs in other ways to cover these additional costs.

We rejected this alternative to apply a 5-year transition schedule because we expect a shorter transition schedule is a more reasonable way for MA organizations to absorb the costs of providing these services and in designing plan benefits. In addition, as discussed in section II.B. of this FC, updated Medicare FFS projections since the February 2020 proposed rule show further increases (for service categories applicable to each of the three cost sharing proposals discussed in this section). However, we clarify that the projected increased costs for emergency services (based on contract year 2023 Medicare FFS data projections) are not factored into the transition of cost sharing limits in Table 35 as the proposal for that service category was based on specific amounts.

Alternative 3 (Finalized): This alternative: (1) shortens the multiyear transition by 1 year (compared to the second alternative discussed in this section); (2) continues to codify the longstanding 20 percent coinsurance limit for the "Part B drugs – other" service category (with

the same 4-year transition); and (3) requires that CMS set copayment limits at an amount that is the lesser of: an actuarially equivalent value to the applicable cost sharing standard or the value resulting from the 4-year actuarially equivalent copayment transition for that service category. The shorter transition schedule results in increases to the copayment limits for contract year 2023 for the service categories shown in Tables 33 through 37 that are generally greater than the second alternative but less than the first alternative. In addition, applying either this alternative or the second alternative discussed in this section also results in the same cost sharing limits for contract year 2023 for certain service categories and MOOP limits (as shown in Tables 33 through 35). However, the differences in applying this alternative or the second alternative discussed in this section, would result in greater differences in the cost sharing limits in the later years of the multiyear transition schedules in most cases.

Our rational for selecting this finalized approach is multifaceted. It—(1) improves the methodology CMS uses to calculate copayment limits to ultimately reflect actuarially equivalent values based on updated Medicare FFS data projections; (2) helps to mitigate potentially substantial increases to cost sharing or premium, and/or benefit reductions if copayment limits are not adjusted to reflect updated Medicare FFS data projections; (3) incentivizes MA organizations to adopt lower MOOP amounts; and (4) implements changes in a transparent, incremental approach to provide more stability and predictability to the MA program. This rationale and the aspects of operationalizing this transition are discussed in greater detail in section II.B. of this FC (for example, see Table 13 for the annual change in coinsurance limits for service categories subject to § 422.100(f)(6)(iii) for contract years 2023 to 2026 and future years). As shown in Table 33, finalizing a 4-year transition to the range of cost sharing limits results in nominal changes for the physical therapy and speech-language pathology service category compared to the second alternative discussed in this section (using the same contract year 2023 Medicare FFS data projections). Specifically, the coinsurance limit for the intermediate and mandatory MOOP limit is 1 percent less than what would be applied if the

second alternative was implemented. This outcome holds true in contract year 2023 for all professional services subject to paragraph (f)(6)(iii) as coinsurance limits are applied consistently across these service categories. As a result of applying a requirement to set copayment limits at the lower value and the rounding rules in paragraph (f)(6)(ii), Table 34 shows that the contract year 2023 partial hospitalization copayment limit for the lower and intermediate MOOP limits changes by \$5 between the second and third alternatives.

Finalizing a 4-year transition does not change the emergency services cost sharing limits in comparison to implementing the second alternative discussed in this section for contract year 2023 (as shown in Table 35). This is due to the rounding rules, which are being applied consistent with the February 2020 proposed rule. CMS calculated the proposed and final emergency services cost sharing limits using those same rounding rules. As discussed in relation to the second alternative in this section, the requirement that CMS set copayment limits at an amount that is the lesser of: (1) an actuarially equivalent value to the applicable cost sharing standard; or (2) the value resulting from the actuarially equivalent copayment transition for that service category does not apply to emergency services.

Table 36 shows how finalizing a 4-year transition also reduces the contract year 2023

Part B drugs – chemotherapy/radiation drugs service category copayment limit compared to the first alternative in this section. Specifically, the increase from the \$75 copayment limit for contract year 2022 changes from a \$205 increase (resulting from the first alternative) to a \$50 increase (this alternative). In addition, the \$125 copayment limit resulting from this alternative only reflects an additional increase of \$10 in comparison to the second alternative discussed in this section (based on the same contract year 2023 Medicare FFS data projections) as a result of applying a requirement to set copayment limits at the lower value and the rounding rules in paragraph (f)(6)(ii).

Table 37 shows how finalizing a 4-year transition from current copayment limits to copayments that are aligned to the longstanding 20 percent coinsurance limit for the "Part B

drugs – other" service category significantly reduces the contract year 2023 copayment limit for this service category compared to the first alternative in this section (based on the same contract year 2023 Medicare FFS data projections). Specifically, the increase to the "Part B drugs – other" service category copayment limit from the prior year (\$50 for contract year 2022) for this alternative is \$70 (for all MOOP types) which is significantly lower than an increase of \$750 in the first alternative for a plan that establishes a lower MOOP amount). In addition, the \$120 copayment limit resulting from this alternative reflects an increase of only \$15 in comparison to the second alternative discussed in this section as a result of applying a requirement to set copayment limits at the lower value and the rounding rules in paragraph (f)(6)(ii).

As discussed previously, the potential administration burden for each service category for which CMS does not set a copayment limit would remain the same. As discussed in the second alternative in this section, if CMS does not apply the methodology and rules in § 422.100(f)(6), (f)(7), (f)(8) and (j) to set a copayment limit during the multiyear transition period for a service category subject to paragraph (f)(6)(iii) or (j)(1), MA organizations may establish copayment amounts for that service category that may be higher or lower than the projected values in Tables 33, 34, 36, and 37, depending on the MA organization's calculation of a value that is an actuarially equivalent to the applicable coinsurance limit.

As a result, CMS calculated and set contract year 2023 copayment limits for the majority of service categories that had copayment limits in contract year 2022 (as shown in Tables 25A, 25B, and 28). Specifically, for benefits subject to § 422.100(j)(1), calculating actuarially equivalent copayment limits based the most recent Medicare FFS data projections available to CMS for these service categories ensures that MA cost sharing does not exceed cost sharing in original Medicare for those benefits. This allows CMS to ensure MA organizations comply with these limits and that the plan cost sharing does not discriminate against or discourage enrollment in an MA plan by beneficiaries who have high health care needs.

We acknowledge that a multiyear transition that is shorter than 4 years, but longer than 1 year as described in the first alternative, would result in more substantial increases to the copayment limits for the service categories subject to §§ 422.100(f)(6)(iii), (j)(1), and 422.113(b)(2)(v) compared to the contract year 2022 limits. For example, a \$5 increase to the partial hospitalization service category copayment limit for the mandatory MOOP limit in comparison to contract year 2022 (as shown in Table 34 for this alternative) is not necessarily substantial by itself. However, CMS considered the combined potential effect of the increases to MOOP limits and copayment limits across service categories. For example, we were especially aware of the substantial increases to the copayment limits for benefits subject to paragraph (j)(1) from contract year 2022 as a result of calculating actuarially equivalent values to the cost sharing in original Medicare using contract year 2023 Medicare FFS data projections based on 2017 – 2021 Medicare FFS data (as shown in Tables 36 and 37) could negatively impact enrollees as described in the introduction to section V.H. of this FC. In addition, prior to this FC, CMS has only updated MOOP limits, inpatient hospital, skilled nursing facility, and emergency services cost sharing limits in recent years. Under this FC, we will be updating MOOP limits and cost sharing limits for most service categories each year during the transition period, which reflects more significant changes to our standards compared to recent years, in order to reach the proposed MOOP and cost sharing limits in a reasonable timeframe.

Based on the considerations discussed in this section, we are implementing this alternative to: (1) codify our longstanding 20 percent coinsurance limit for the "Part B drugs – other" service category; (2) apply a 4-year transition to reach the proposed cost sharing standards (for professional services, emergency services, and benefits for which cost sharing must not exceed cost sharing in original Medicare); and (3) require that CMS set copayment limits at an amount that is the lesser of: an actuarially equivalent value to the applicable cost sharing standard or the value resulting from the 4-year actuarially equivalent copayment transition for that service category. We expect implementing the policies based on this alternative will (for the

reasons discussed in this section and in section II.B. of this FC: (1) ensure beneficiary access to affordable and sustainable benefit packages; (2) protect enrollees from discriminatory levels of cost sharing; (3) limit potential rapid cost and benefit changes; (4) encourage MA organizations to establish lower MOOP amounts; and (5) streamline the updates to MOOP limit and cost sharing requirements, which will also provide stability for MA organizations. We reiterate that the copayment limits set for contract year 2022 have been in place for a number of years and that CMS expects that this 4-year transition to the proposed cost sharing limits will ultimately result in stable benefit packages by ensuring limits are calculated following established actuarial methods, using the most recent Medicare FFS data projections available, and by aligning copayment limits with coinsurance limits. In other words, CMS is making the changes necessary to reach actuarially equivalent copayments that reflect plan costs associated with the variety and expense of services included in the cost sharing limit while protecting beneficiaries from discriminatory levels of cost sharing.

TABLE 33: CONTRACT YEAR 2023 IN-NETWORK PHYSICAL THERAPY AND SPEECH-LANGUAGE PATHOLOGY SERVICE CATEGORY COST SHARING LIMITS AS AN ILLUSTRATIVE COMPARISON OF ALTERNATIVES AND FINALIZED METHODOLOGY TO TRANSITION CONTRACT YEAR 2022 COST SHARING LIMITS FOR SERVICE CATEGORIES SUBJECT TO A RANGE OF COST SHARING LIMITS BASED ON MOOP TYPE USING CONTRACT YEAR 2023 MEDICARE FFS DATA PROJECTIONS (BASED ON 2017 – 2021 MEDICARE FFS DATA)

Range of Cost Sharing Limits Implementation	Lower	Intermediate	Mandatory
Baseline: Contract Year 2022 Limits	50% / \$40	N/A	50% / \$40
Alternative 1: Apply range of cost sharing as proposed beginning in contract year 2023	50% / \$90	40% / \$70	30% / \$55
Alternative 2: Apply a 5-year transition to the range of cost sharing limits proposed	50% / \$50	48% / \$45	46% / \$45
Alternative 3 (Finalized): Apply a 4-year transition to the range of cost sharing limits proposed	50% / \$50	47% / \$50	45% / \$45

TABLE 34: CONTRACT YEAR 2023 IN-NETWORK PARTIAL HOSPITALIZATION SERVICE CATEGORY COST SHARING LIMITS AS AN ILLUSTRATIVE COMPARISON OF ALTERNATIVES AND FINALIZED METHODOLOGY TO TRANSITION CONTRACT YEAR 2022 COST SHARING LIMITS FOR SERVICE CATEGORIES SUBJECT TO A RANGE OF COST SHARING LIMITS BASED ON MOOP TYPE USING CONTRACT YEAR 2023 MEDICARE FFS DATA PROJECTIONS (BASED ON 2017 – 2021 MEDICARE FFS DATA)

Range of Cost Sharing Limits Implementation	Lower	Intermediate	Mandatory
Baseline: Contract Year 2022 Limits	50% / \$55	N/A	50% / \$55
Alternative 1: Apply range of cost sharing as proposed beginning in contract year 2023	50% / \$135	40% / \$110	30% / \$80
Alternative 2: Apply a 5-year transition to the range of cost sharing limits proposed	50% / \$70	48% / \$65	46% / \$60
Alternative 3 (Finalized): Apply a 4-year transition to the range of cost sharing limits proposed	50% / \$75	47% / \$70	45% / \$60

TABLE 35: CONTRACT YEAR 2023 EMERGERCY SERVICES COST SHARING LIMITS AS AN ILLUSTRATIVE COMPARISON OF ALTERNATIVES AND FINALIZED METHODOLOGY TO TRANSITION CONTRACT YEAR 2022 COPAYMENT LIMITS TO PROPOSED COST SHARING LIMITS

Emergency Services Cost Sharing Limits	Lower	Intermediate	Mandatory
Baseline: Contract Year 2022 Limits	\$120	N/A	\$90
Alternative 1: Apply cost sharing limits as proposed beginning in contract year 2023	\$150	\$130	\$115
Alternative 2: Apply a 5-year transition to proposed copayment limits	\$125	\$110	\$95
Alternative 3 (Finalized): Apply a 4-year transition to proposed copayment limits	\$125	\$110	\$95

TABLE 36: CONTRACT YEAR 2023 IN-NETWORK PART B DRUGS:
CHEMOTHERAPY/RADIATION DRUGS SERVICE CATEGORY COST SHARING
LIMITS AS AN ILLUSTRATIVE COMPARISON OF ALTERNATIVES AND
FINALIZED METHODOLOGY TO TRANSITION CONTRACT YEAR 2022
COPAYMENT LIMITS FOR SERVICE CATEGORIES SUBJECT TO § 422.100(j)(1)
TO ACTUARIALLY EQUIVALENT VALUES TO COST SHARING IN ORIGINAL
MEDICARE USING CONTRACT YEAR 2023 MEDICARE FFS DATA PROJECTIONS
(BASED ON 2017 – 2021 MEDICARE FFS DATA)

Services for which Cost Sharing Must Not Exceed Cost Sharing under Original Medicare	All MOOP Limits
Baseline: Contract Year 2022 Limits	20% / \$75
Alternative 1: No copayment limits, MA organizations have the burden to determine actuarially equivalent copayment values	20% / \$280
Alternative 2: Apply a 5-year transition to actuarially equivalent copayment limits	20% / \$115
Alternative 3 (Finalized): Apply a 4-year transition to actuarially equivalent copayment limits	20% / \$125

TABLE 37: CONTRACT YEAR 2023 IN-NETWORK PART B DRUGS: OTHER SERVICE CATEGORY COST SHARING LIMITS AS AN ILLUSTRATIVE COMPARISON OF ALTERNATIVES AND FINALIZED METHODOLOGY TO TRANSITION CONTRACT YEAR 2022 COPAYMENT LIMITS FOR SERVICE CATEGORIES SUBJECT TO § 422.100(j)(1) TO ACTUARIALLY EQUIVALENT VALUES TO COST SHARING IN ORIGINAL MEDICARE USING CONTRACT YEAR 2023 MEDICARE FFS DATA PROJECTIONS (BASED ON 2017 – 2021 MEDICARE FFS DATA)

Services for Which Cost Sharing Must Not Exceed Cost Sharing under Original Medicare	Lower	Intermediate	Mandatory
Baseline: Contract Year 2022 Limits	20% / \$50	N/A	20% / \$50
Alternative 1: Apply range of cost sharing as proposed beginning in contract year 2023	50% / \$800	40% / \$640	30% / \$480

Alternative 2: Apply a 5-year transition to copayment limits that are actuarially equivalent to original Medicare	20% / \$105	20% / \$105	20% / \$105
Alternative 3 (Finalized): Apply a 4-year transition to copayment limits that are actuarially equivalent to original Medicare	20% / \$120	20% / \$120	20% / \$120

I. Accounting Statement

This FC rule finalizes provisions on the coinsurance and copayment limits for professional service categories, the cost sharing limits for emergency services, copayment limits for service categories for which cost sharing must not exceed cost sharing under original Medicare, and presents a multiyear transition for ESRD costs for MOOP limits and inpatient hospital cost sharing limits. As discussed in this RIA section, a combination of three reasons drives the conclusion that in aggregate this FC has no cost: (1) the MA requirement of actuarial equivalence to coverage in original Medicare, implying that plans can shift costs, but not create additional out of pocket costs for enrollees compared to the original Medicare program; (2) many of the provisions of this FC are codifications of existing practice, which because of the annual bid cycle and review, we are confident plans are complying with; and (3) with regard to the MOOP provisions, analysis of bid changes shows that plans in general have not been charging the highest MOOP amount.

As a result, although in aggregate there is no estimated impact, Medicare Advantage plans may shift cost sharing costs provided they do not create additional costs. This is because actuarial equivalence refers to an equivalence with all original Medicare beneficiaries and all services provided by original Medicare. It follows, that a more detailed analysis on particular cohorts of enrollees and particular collections of services may reveal gains or losses to these groups. Because of the challenges with making such an analysis, including the proprietary nature of bids, we are unable to provide quantification in this FC; however, because of the possibility that some of these cohorts might have a gain or loss exceeding the threshold, we have classified this rule as major.

This summary serves as the accounting statement required by Circular A-4.

J. Conclusion

This FC makes policy changes in alignment with federal laws related to the Medicare Advantage (MA or Part C) program from the 21st Century Cures Act (Pub. L.114-255). The rule also includes regulatory changes to strengthen and improve the Part C program by codifying in regulation several CMS policies previously adopted through the annual Call Letter and other guidance documents to interpret and implement rules regarding benefits in MA plans. The provisions in this FC do not have an aggregate cost impact.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on February 8, 2022.

List of Subjects

42 CFR Part 422

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

PART 422—MEDICARE ADVANTAGE PROGRAM

1. The authority citation for part 422 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

- * * * * *
- 2. Section 422.100 is amended by--
- a. Adding paragraph headings for paragraphs (f)(1) through (3);
- b. Revising paragraphs (f)(4) through (6);
- c. Adding paragraphs (f)(7), (8), and (9); and
- d. Revising paragraph (j).

The revisions and additions read as follows:

§ 422.100 General requirements.

- * * * * *
 - (f) * * *
 - (1) Guidelines. * * *
 - (2) Discrimination. * * *
 - (3) Other requirements. * * *
- (4) *In-network MOOP limit*. Except as provided in paragraph (f)(5) of this section, MA local plans (as defined in § 422.2) must have an enrollee in-network maximum out-of-pocket (MOOP) amount for basic benefits that is no greater than the annual limit calculated by CMS using Medicare Fee-for-Service (FFS) data projections. With respect to a private fee-for-service (PFFS) plan, the in-network MOOP limits specified in this paragraph (f)(4) apply. MA organizations are responsible for tracking out-of-pocket spending incurred by the enrollee, and

must alert enrollees and contracted providers when the plan's in-network MOOP amount is reached.

- (i) Medicare FFS data projections in CMS MOOP limit calculations. For each year beginning on or after January 1, 2023, CMS calculates three MOOP limits using Medicare FFS data projections. For purposes of this paragraph (f)(4) and calculating actuarially equivalent copayments as described in paragraph (f)(7) of this section, the term Medicare FFS data projections means the projections of beneficiary out-of-pocket costs for the applicable contract year, based on recent Medicare FFS data, including data for beneficiaries with and without diagnoses of ESRD, that are consistent with generally accepted actuarial principles and practices as outlined in paragraph (f)(7)(i) of this section. The dollar ranges for the three MOOP limits are as follows:
- (A) *Mandatory MOOP limit*. One dollar above the intermediate MOOP limit and up to and including the mandatory MOOP limit.
- (B) *Intermediate MOOP limit*. One dollar above the lower MOOP limit and up to and including the intermediate MOOP limit.
 - (C) Lower MOOP limit. Between \$0.00 and up to and including the lower MOOP limit.
- (ii) MOOP type. An MA organization that establishes a plan's MOOP amount within the dollar range specified in paragraphs (f)(4)(i)(A) through (C) of this section has the corresponding mandatory, intermediate, or lower MOOP type for purposes of paragraphs (f) and (j) of this section and §§ 422.101(d) and 422.113(b)(2)(v).
- (iii) *CMS rounding of MOOP limits*. Each MOOP limit CMS calculates is rounded to the nearest \$50 increment and in cases where the MOOP limit is projected to be exactly in between two \$50 increments, CMS rounds to the lower \$50 increment.
- (iv) MOOP limits for 2023. For 2023, CMS calculates the MOOP limits as follows, applying paragraph (f)(4)(vi)(A) of this section:

- (A) *Mandatory MOOP limit*. \$7,175 (the 95th percentile of projected contract year 2021 Medicare FFS beneficiary out-of-pocket spending for beneficiaries without diagnoses of ESRD) plus 70 percent of the ESRD cost differential unless: the resulting MOOP limit (after application of the rounding rules in paragraph (f)(4)(iii) of this section) reflects an increase greater than 10 percent compared to the mandatory MOOP limit from the prior year, in which case CMS caps the increase to the mandatory MOOP limit by 10 percent of the prior year's MOOP limit.
- (B) *Intermediate MOOP limit*. The numeric midpoint between the mandatory and lower MOOP limits (calculated before application of the rounding rules in paragraph (f)(4)(iii) of this section and after application of the 10 percent cap on increases to the mandatory and lower MOOP limits from the prior year in paragraphs (f)(4)(iv)(A) and (C) of this section).
- (C) Lower MOOP limit. \$3,360 (the 85th percentile of projected contract year 2021 Medicare FFS beneficiary out-of-pocket spending for beneficiaries without diagnoses of ESRD) plus 70 percent of the ESRD cost differential unless: the resulting MOOP limit (after application of the rounding rules in paragraph (f)(4)(iii) of this section) reflects an increase greater than 10 percent compared to the voluntary MOOP limit from the prior year, in which case CMS caps the increase to the lower MOOP limit by 10 percent of the prior year's MOOP limit.
- (v) MOOP limits for 2024 and subsequent years. For 2024 and subsequent years, CMS annually calculates the MOOP limits as follows, applying paragraph (f)(4)(vi)(B) of this section:
- (A) *Mandatory and lower MOOP limits*. The prior year's MOOP limits are increased or decreased for the upcoming contract year to reflect the applicable percentiles (95th for the mandatory MOOP and 85th for the lower MOOP) of the Medicare FFS data projections unless: either of the resulting MOOP limits reflect an increase greater than 10 percent compared to the same type of MOOP limit from the prior year, in which case CMS caps the increase to the applicable MOOP limit(s) by 10 percent of the prior year's MOOP limit annually until the MOOP limit(s) reflects the applicable percentile(s).

- (B) Intermediate MOOP limit. Is either maintained at the prior year's limit or if either the mandatory or lower MOOP limit changes from the prior year, updated to the new numeric midpoint between the mandatory and lower MOOP limits (calculated before application of the rounding rules in paragraph (f)(4)(iii) of this section and after application of the 10-percent cap on increases to the mandatory and lower MOOP limits from the prior year in paragraph (f)(4)(v)(A) of this section).
- (vi) *CMS calculation of the ESRD cost differential*. For purposes of the ESRD cost transition methodology to calculate annual MOOP limits contained in this section, the *ESRD cost differential* is the difference between, first, for the mandatory MOOP limit, \$7,175 and for the lower MOOP limit, \$3,360 and second, for the mandatory MOOP limit, the 95th percentile and, for the lower MOOP limit, the 85th percentile of the Medicare FFS data projections for each year between 2023 and 2024. CMS transitions to using the Medicare FFS data projections by factoring in a percentage of the ESRD cost differential on the following schedule:
- (A) For 2023, CMS uses projected Medicare FFS beneficiary out-of-pocket spending for beneficiaries without diagnoses of ESRD plus 70 percent of the ESRD cost differential.
 - (B) For 2024 and subsequent years, CMS uses the Medicare FFS data projections.
- (5) Combined MOOP limit. With respect to a local PPO plan, the MOOP limits specified under paragraph (f)(4) of this section apply only to use of in-network providers.
- (i) Combined and total catastrophic MOOP limits. MA local PPO plans must establish a combined enrollee MOOP amount for basic benefits that are provided in-network and out-of-network that is no greater than the total catastrophic limit applicable to regional plans in § 422.101(d)(3).
- (ii) *In-network and combined MOOP type*. The type of in-network MOOP limit dictates the type of combined MOOP limit the MA plan may use. MA PPO plans must have the same MOOP type (lower, intermediate, or mandatory) for the in-network MOOP limit and combined limit on in-network and out-of-network out-of-pocket expenditures.

- (iii) *MOOP limit attainment*. MA organizations are responsible for tracking out-of-pocket spending incurred by the enrollee and must alert enrollees and contracted providers when the combined MOOP amount is reached.
- (6) General cost sharing limits. Cost sharing for basic benefits specified by CMS does not exceed levels annually determined by CMS to be discriminatory for such services. For each year beginning on or after January 1, 2023, a MA organization must establish cost sharing for basic benefits that complies with the cost sharing limits in this paragraph (f)(6), paragraph (j) of this section, and § 422.113(b)(2), which are in addition to any other limits and rules applicable to MA cost sharing, including the requirement in § 422.254(b)(4) that overall MA cost sharing for basic benefits be actuarially equivalent to Medicare FFS cost sharing. Cost sharing may be a coinsurance or copayment; a cost sharing limit is calculated for a plan benefit package service category or for a reasonable group of benefits covered under the plan. For purposes of cost sharing evaluation, the analysis is completed at the plan (or segment) level. An MA plan must not charge an enrollee a copayment for a basic benefit that is greater than the cost of the covered service(s).
- (i) The 50 percent cap on original Medicare benefits. For in-network basic benefits that are not specifically addressed in this paragraph (f)(6), paragraph (f)(1) of this section, or § 422.113(b)(2), and for out-of-network basic benefits, MA plans must not establish a cost sharing amount that exceeds 50 percent coinsurance or an actuarially equivalent copayment value (calculated by CMS following the requirements in paragraph (f)(7) of this section or, if CMS does not calculate a copayment limit, based on the average Medicare FFS allowable amount for the plan service area or the estimated total MA plan financial liability for the service category or for a reasonable group of benefits in the PBP for that contract year). The rules in this paragraph (f)(6)(i) apply regardless of the type of MOOP limit established by the plan.

- (ii) Copayment rounding rules. The following rounding rules apply in calculating copayment limits and in evaluating compliance with this paragraph (f)(6) and paragraphs (f)(7), (f)(8), and (j)(1) of this section:
- (A) For service categories subject to paragraph (f)(6)(i) of this section, professional services subject to paragraph (f)(6)(iii) of this section, and benefits listed in paragraph (j)(1)(i) of this section, the final actuarially equivalent copayment value is rounded to the nearest whole \$5.
- (B) For inpatient hospital acute and psychiatric and skilled nursing facility cost sharing limits subject to paragraphs (f)(6)(iv) and (j)(1)(i)(C) of this section, the final actuarially equivalent copayment value is rounded to the nearest whole \$1.
- (C) When the actuarially equivalent copayment value is projected to be exactly between two increments, the final figure is rounded to the lower dollar amount.
- (iii) Cost sharing limits for professional services. (A) For in-network basic benefits that are professional services, including primary care services, physician specialist services, partial hospitalization, and rehabilitation services, an MA plan must not establish cost sharing that exceeds the limits in this paragraph (f)(6)(iii) for the MOOP limit established by the MA plan.
- (B) When calculating copayment limits for purposes of this paragraph, CMS calculates an actuarially equivalent value to the coinsurance limits in this paragraph (f)(6)(iii), subject to the requirements in paragraph (f)(7) of this section and the restrictions on increases to copayment limits in paragraph (f)(8) of this section. If CMS does not calculate a copayment limit for a professional service category, the MA plan must not establish a copayment that exceeds the actuarially equivalent value to the coinsurance limits in this paragraph (f)(6)(iii) based on the estimated total MA plan financial liability for that benefit for that contract year.
- (C) For 2023, MA plans must not exceed the cost sharing limits for professional service categories, as follows:

- (1) Mandatory MOOP limit. 45 percent coinsurance or an actuarially equivalent copayment value and the MA plan must not pay less than 55 percent of the estimated total MA plan financial liability for the benefit.
- (2) Intermediate MOOP limit. 47 percent coinsurance or an actuarially equivalent copayment value and the MA plan must not pay less than 53 percent of the estimated total MA plan financial liability for the benefit.
- (3) Lower MOOP limit. 50 percent coinsurance or an actuarially equivalent copayment value and the MA plan must not pay less than 50 percent of the estimated total MA plan financial liability.
- (D) For 2024, MA plans must not exceed the cost sharing limits for professional service categories, as follows:
- (1) Mandatory MOOP limit. 40 percent coinsurance or an actuarially equivalent copayment value and the MA plan must not pay less than 60 percent of the estimated total MA plan financial liability for the benefit.
- (2) Intermediate MOOP limit. 45 percent coinsurance or an actuarially equivalent copayment value and the MA plan must not pay less than 55 percent of the estimated total MA plan financial liability for the benefit.
- (3) Lower MOOP limit. 50 percent coinsurance or an actuarially equivalent copayment value and the MA plan must not pay less than 50 percent of the estimated total MA plan financial liability.
- (E) For 2025, MA plans must not exceed the cost sharing limits for professional service categories, as follows:
- (1) Mandatory MOOP limit. 35 percent coinsurance or an actuarially equivalent copayment value and the MA plan must not pay less than 65 percent of the estimated total MA plan financial liability for the benefit.

- (2) Intermediate MOOP limit. 42 percent coinsurance or an actuarially equivalent copayment value and the MA plan must not pay less than 58 percent of the estimated total MA plan financial liability for the benefit.
- (3) Lower MOOP limit. 50 percent coinsurance or an actuarially equivalent copayment value and the MA plan must not pay less than 50 percent of the estimated total MA plan financial liability.
- (F) For 2026 and subsequent years, MA plans must not exceed the cost sharing limits for professional service categories, as follows:
- (1) Mandatory MOOP limit. 30 percent coinsurance or an actuarially equivalent copayment value and the MA plan must not pay less than 70 percent of the estimated total MA plan financial liability for the benefit.
- (2) Intermediate MOOP limit. 40 percent coinsurance or an actuarially equivalent copayment value and the MA plan must not pay less than 60 percent of the estimated total MA plan financial liability for the benefit.
- (3) Lower MOOP limit. 50 percent coinsurance or an actuarially equivalent copayment value and the MA plan must not pay less than 50 percent of the estimated total MA plan financial liability.
- (iv) Inpatient hospital acute and psychiatric service category cost sharing limits. (A) For in-network basic benefits that are inpatient hospital acute and psychiatric service categories, an MA plan must not establish cost sharing that exceeds the limits calculated by CMS under paragraph (f)(6)(iv) of this section and subject to paragraph (f)(7) of this section for the MOOP limit established by the MA plan.
- (B) Cost sharing limits for inpatient hospital acute and psychiatric service categories are calculated for the following seven length-of-stay scenarios for a period for which cost sharing would apply under original Medicare: inpatient hospital acute stay scenarios of 3 days, 6 days,

10 days, and 60 days and inpatient hospital psychiatric stay scenarios of 8 days, 15 days, and 60 days.

- (C) CMS calculates the inpatient hospital acute and psychiatric service category cost sharing limits annually using projections of Medicare FFS out-of-pocket costs and utilization for the applicable year and length of stay scenario and factors in out-of-pocket costs incurred by beneficiaries with diagnoses of ESRD on the transition schedule described in paragraphs (f)(4)(vi)(A) through (B) of this section and may also use patient utilization information from MA encounter data.
- (D) Provided that the total cost sharing for the inpatient benefit does not exceed the MA plan's MOOP limit or overall cost sharing for inpatient benefits in original Medicare on a per member per month actuarially equivalent basis, cost sharing applicable to inpatient hospital acute and psychiatric service categories is permitted up to the following limits (based on original Medicare cost sharing for a new benefit period):
- (1) Mandatory MOOP limit. Cost sharing must not exceed 100 percent of estimated Medicare FFS cost sharing, including the projected Part A deductible and related Part B costs, for each length-of-stay scenario.
- (2) Intermediate MOOP limit. Cost sharing must not exceed the numeric midpoint between the cost sharing limits established in paragraphs (f)(6)(iv)(D)(1) and (3) of this section for the same inpatient hospital length of stay scenario, before application of the rounding rules in paragraph (f)(6)(ii) of this section.
- (3) Lower MOOP limit. Cost sharing must not exceed 125 percent of estimated Medicare FFS cost sharing, including the projected Part A deductible and related Part B costs, for each length of stay scenario other than the inpatient hospital acute 60-day length-of-stay for MA plans that establish a lower MOOP limit. For inpatient hospital acute 60-day length of stays, MA plans that establish a lower MOOP limit have the flexibility to establish cost sharing above 125 percent of estimated Medicare FFS cost sharing.

- (7) Using generally accepted actuarial principles and practices. (i) Application of generally accepted actuarial principles and practices. The projections and calculations used in the methodologies described in paragraphs (f)(4), (f)(5), (f)(6), (f)(7)(ii), (f)(8), and (j) of this section and in § 422.101(d)(2) and (3) must be made using generally accepted actuarial principles and practices.
- (A) In applying generally accepted actuarial principles and practices, actuarial judgment and discretion may be used, including taking into account information such as changes in legislation (such as changes in Medicare benefits), Medicare payment policy, trends over several years of data, and external variables (such as public health emergencies); selecting among different approaches (such as weighting for utilization and using average or median values); and in selecting data or data samples.
- (B) MA organizations must use generally accepted actuarial principles and practices in complying with the regulations in paragraphs (f)(6) and (j) of this section.
- (C) CMS applies generally accepted actuarial principles and practices in evaluating MA plan compliance with paragraphs (f)(6) and (j) of this section.
- (ii) CMS calculation of actuarially equivalent copayment limits. As feasible and appropriate to carry out program purposes, CMS calculates copayment limits for basic benefits in accordance with paragraphs (f)(6)(i) and (iii) and (j)(1) of this section. Beginning January 1, 2023, unless specified otherwise in paragraphs (f)(6) and (j)(1) of this section, CMS calculates these copayment limits at an actuarially equivalent value to the cost sharing standard as follows:
- (A) Using Medicare FFS data projections, as defined in paragraph (f)(4)(i) of this section, for the applicable year and service category.
- (B) Using patient utilization information from MA encounter data, in addition to the Medicare FFS data projections (including cost and utilization data), if available and where appropriate to consider utilization differences between Medicare FFS beneficiaries and MA

enrollees to reach a value that most closely reflects an actuarially equivalent copayment for the benefit and beneficiary population.

- (C) Selecting a particular approach to calculate an actuarially equivalent copayment value in situations where there may be multiple or a range of actuarially equivalent copayment values for a service category in order to carry out program purposes, including: setting copayment limits that most closely reflect an actuarially equivalent copayment for the benefit and beneficiary population, protecting against discriminatory cost sharing, and avoiding unnecessary fluctuations in cost sharing that may confuse beneficiaries.
- (D) Applying the actuarially equivalent copayment transition in paragraph (f)(8) of this section.
 - (E) Applying rounding rules in paragraph (f)(6)(ii) of this section.
- (iii) *CMS issuance of annual guidance*. CMS issues guidance that specifies the MOOP limits and cost sharing standards for the upcoming contract year (beginning with contract year 2024) that are set and calculated using the methodology and standards in paragraphs (f) and (j) of this section and §§ 422.101(d) and 422.113. This guidance is released prior to bid submission to allow sufficient time for MA organizations to prepare and submit plan bids. Unless a public comment period is impracticable, unnecessary, or contrary to the public interest, CMS provides a public notice and comment period on the projected MOOP limits and cost sharing standards for the upcoming contract year.
- (8) Annual cap on CMS increasing copayment limits during the actuarially equivalent copayment transition. For 2023 through 2025, CMS sets a copayment limit for a service category subject to paragraph (f)(6)(iii) or (j)(1) of this section at an amount that is the lesser of an actuarially equivalent value to the applicable cost sharing standard (from paragraph (f)(6)(iii) or (j)(1) of this section) or the value resulting from the actuarially equivalent copayment transition in paragraph (f)(8)(ii) of this section for that service category.

- (i) CMS calculation of the actuarially equivalent copayment differential. For purposes of this section, the actuarially equivalent copayment differential is as follows:
- (A) For cost sharing at the mandatory and lower MOOP limits, the difference between, first, the copayment limit set for a plan benefit package service category based on the MOOP type for 2022 and second, the copayment value for the same service category that is actuarially equivalent to the coinsurance limits in paragraphs (f)(6)(iii) and (j)(1) of this section that apply in 2026 based on the MOOP type, using the Medicare FFS data projections that are updated each year to reflect the costs of the contract year for which the copayment limit will apply.
- (B) For cost sharing at the intermediate MOOP limit, the difference between, first, the copayment limit set for a plan benefit package service category based on the mandatory MOOP type for 2022 and second, the copayment value for the same service category that is actuarially equivalent to the coinsurance limits in paragraphs (f)(6)(iii) and (j)(1) of this section that apply in 2026 for the intermediate MOOP type, using the Medicare FFS data projections that are updated each year to reflect the costs of the contract year for which the copayment limit will apply.
- (ii) CMS's actuarially equivalent copayment transition. For service categories subject to the cost sharing standards in paragraphs (f)(6)(iii) and (j)(1) of this section, copayment limits calculated by CMS for 2023 through 2025 are capped at the amounts calculated under this paragraph, unless specified otherwise in paragraph (f)(8) of this section, rounded as provided in paragraph (f)(6)(ii) of this section:
- (A) For 2023, CMS uses the copayment limits set for 2022 plus 25 percent of the actuarially equivalent copayment differential.
- (B) For 2024, CMS uses the copayment limits set for 2022 plus 50 percent of the actuarially equivalent copayment differential.
- (C) For 2025, CMS uses the copayment limits set for 2022 plus 75 percent of the actuarially equivalent copayment differential.

- (D) For 2026 and subsequent years, CMS calculates service category copayment limits at the projected actuarially equivalent value to the cost sharing standards in paragraphs (f)(6)(iii)(F) and (j)(1) of this section and subject to paragraph (f)(7) of this section.
- (9) Bundled cost sharing. Cost sharing (copayments and coinsurance) for basic benefits must reflect the enrollee's entire cost sharing responsibility, inclusive of professional, facility, or provider setting charges, by combining (or bundling) all applicable fees into the cost sharing amount for that particular service(s) and setting(s) and be clearly reflected as a single, total cost sharing in appropriate materials distributed to beneficiaries for basic benefits.

* * * * *

- (j) Cost sharing and actuarial equivalence standards for basic benefits--(1) Specific benefits for which cost sharing may not exceed cost sharing under original Medicare. (i)

 General rule. For each year beginning on or after January 1, 2023, in-network cost sharing established by an MA plan for the basic benefits listed in this paragraph may not exceed the cost sharing required under original Medicare. When an MA plan uses coinsurance, the coinsurance must not exceed the coinsurance charged in original Medicare. When an MA plan uses copayments, the copayment must not exceed the actuarially equivalent value calculated using the rules in paragraph (j)(1)(ii) of this section. The benefits listed in this paragraph are as follows:
- (A) Chemotherapy administration services to include chemotherapy/radiation drugs and radiation therapy integral to the treatment regimen.
 - (B) Renal dialysis services as defined at section 1881(b)(14)(B) of the Act.
- (C) Skilled nursing care, defined as services provided during a covered stay in a skilled nursing facility during the period for which cost sharing would apply under original Medicare, when the MA plan establishes the mandatory MOOP type; when the MA plan establishes the lower MOOP type, the cost sharing must not be greater than \$20 per day for the first 20 days of a SNF stay; when the MA plan establishes the intermediate MOOP type, the cost sharing must not be greater than \$10 per day for the first 20 days of a SNF stay.

- (1) Regardless of the MOOP amount established by the MA plan, the per-day cost sharing for days 21 through 100 must not be greater than one eighth of the projected (or actual) Part A deductible amount.
- (2) Total cost sharing for the overall SNF benefit must not be greater than the per member per month actuarially equivalent cost sharing for the SNF benefit in original Medicare.
- (D) Home health services (as defined in section 1861(m) of the Act), when the MA plan establishes a mandatory or intermediate MOOP type; when the MA plan establishes the lower MOOP type, the cost sharing must not be greater than 20 percent coinsurance or an actuarially equivalent copayment.
- (E) The following specific service categories of durable medical equipment (DME): equipment, prosthetics, medical supplies, diabetes monitoring supplies, diabetic shoes or inserts when the MA plan establishes the mandatory MOOP limit. For all MOOP limits, total cost sharing for the overall DME benefit must not be greater than the per member per month actuarially equivalent cost sharing for the DME benefit in original Medicare.
- (F) Other drugs covered under Part B of original Medicare (that is, Part B drugs not included in paragraph (j)(1)(i)(A) of this section).
- (ii) Rules for calculating copayment limits. For 2023 and subsequent years, CMS calculates copayment limits for the basic benefits listed in paragraph (j)(1)(i) of this section subject to the requirements in paragraph (f)(7) of this section and the restrictions on increases to copayment limits in paragraph (f)(8) of this section. If CMS does not calculate a copayment limit for a benefit listed in paragraph (j)(1)(i) of this section, an MA plan must establish a copayment that does not exceed an actuarially equivalent value to the coinsurance required under original Medicare; such actuarially equivalent value must be established in accordance with paragraph (f)(7)(i) of this section and based on the average Medicare FFS allowed amount in the plan's service area or the estimated total MA plan financial liability for that benefit for that contract year.

- (2) Actuarially equivalent cost sharing evaluation for all basic benefits and specific categories of basic benefits in the aggregate. For each year beginning on or after January 1, 2023, an MA plan's total cost sharing for all basic benefits, excluding out of network benefits covered by a regional MA plan, must not exceed cost sharing for those benefits in original Medicare on a per member per month actuarially equivalent basis.
- (i) MA plans must have cost sharing for the following specific benefit categories that does not exceed the cost sharing for those benefit categories in original Medicare on a per member per month actuarially equivalent basis:
- (A) Inpatient hospital acute and psychiatric services, defined as services provided during a covered inpatient stay during the period for which cost sharing would apply under original Medicare.
 - (B) Durable medical equipment (DME).
 - (C) Drugs and biologics covered under Part B of original Medicare.
- (D) Skilled nursing care, defined as services provided during a covered stay in a skilled nursing facility during the period for which cost sharing would apply under original Medicare.
- (ii) CMS may extend flexibility for MA plans when evaluating compliance with the requirements in paragraph (j)(2)(i) of this section regarding actuarial equivalent cost sharing for all basic benefits and specific categories of basic benefits to the extent that it is actuarially justifiable provided that the MA plan's cost sharing is based on generally accepted actuarial principles and practices (consistent with paragraph (f)(7) of this section), supporting documentation included in the bid, and the MA plan's cost sharing for specific service categories otherwise satisfies applicable cost sharing standards.

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3. Amend § 422.101 by revising paragraphs (d)(2) and (3) to read as follows: § 422.101 Requirements relating to basic benefits.

* * * * *

(d) * * *

- (2) *Catastrophic limit*. For each year beginning on or after January 1, 2023, MA regional plans must do the following:
- (i) Establish a catastrophic enrollee MOOP amount for basic benefits that are furnished by in-network providers that is consistent with § 422.100(f)(4).
- (ii) Have the same MOOP type (lower, intermediate, or mandatory) for the catastrophic (in-network MOOP) limit and total catastrophic (combined in-network and out-of-network expenditures) limit under paragraph (d)(3) of this section.
- (3) *Total catastrophic limit*. For each year beginning on or after January 1, 2023, MA regional plans must establish a total catastrophic (combined in-network and out-of-network expenditures) enrollee MOOP amount for basic benefits that is consistent with this paragraph (d)(3).
- (i) The total catastrophic limit may not be used to increase the catastrophic limit described in paragraph (d)(2) of this section.
- (ii) CMS calculates the total catastrophic limits by multiplying the respective in-network MOOP limits (before the rounding rules in § 422.100(f)(4)(iii) are applied and after application of the 10 percent cap on increases to the mandatory and lower MOOP limits from the prior year in § 422.100(f)(4)(iv) and (v)) by 1.5 for the relevant year, then applying the rounding rules in § 422.100(f)(4)(iii). The dollar ranges for the three total catastrophic MOOP limits are as follows:
- (A) *Mandatory MOOP limit*. One dollar above the in-network intermediate MOOP limit and up to and including the total catastrophic mandatory MOOP limit.
- (B) *Intermediate MOOP limit*. One dollar above the in-network lower MOOP limit and up to and including the total catastrophic intermediate MOOP limit.
- (C) Lower MOOP limit. Between \$0.00 and up to and including the total catastrophic lower MOOP limit.

- (iii) An MA organization must establish the total catastrophic MOOP amount (mandatory, intermediate, or lower) within the dollar range specified in paragraphs (d)(3)(ii)(A) through (C) of this section for purposes of paragraph (d) of this section and §§ 422.100(f)(6), (j)(1), and 422.113(b)(2)(v).
 - * * * * *
 - 4. Section 422.113 is amended by—
 - a. Revising paragraph (b)(2)(v); and
 - b. Adding paragraph (b)(2)(vi).

The revision and addition read as follows:

§ 422.113 Special rules for ambulance services, emergency and urgently needed services, and maintenance and post-stabilization care services.

- * * * * *
- (b) * * *
- (2) * * *
- (v) With a dollar limit on emergency services costs for enrollees that is the lower of-
- (A) The cost sharing established by the MA plan if the emergency services were provided through the MA organization; or
- (B) A maximum cost sharing limit permitted per visit that corresponds to the MA plan MOOP limit as follows:
- (1) For 2023, \$95 for a mandatory MOOP limit, \$110 for an intermediate MOOP limit, and \$125 for a lower MOOP limit.
- (2) For 2024, \$100 for a mandatory MOOP limit, \$120 for an intermediate MOOP limit, and \$135 for a lower MOOP limit.
- (3) For 2025, \$110 for a mandatory MOOP limit, \$125 for an intermediate MOOP limit, and \$140 for a lower MOOP limit.

- (4) For 2026 and subsequent years, \$115 for a mandatory MOOP limit, \$130 for an intermediate MOOP limit, and \$150 for a lower MOOP limit.
- (vi) For each year beginning on or after January 1, 2023, with a cost sharing limit on urgently needed services that does not exceed the limits specified for professional services in § 422.100(f)(6)(iii).

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Dated: April 5, 2022.	
	Xavier Becerra,
	Secretary,

<u>Department of Health and Human Services</u>.

[FR Doc. 2022-07642 Filed: 4/7/2022 4:15 pm; Publication Date: 4/14/2022]